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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	11/08/2016	9486407	ADAR-119/02US 325049-2959	3674

91543 7590 10/19/2016
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Stephen PERRETT, Princeton, NJ;
ADARE PHARMACEUTICALS, INC., LAWRENCEVILLE, NJ;
Fredric Jay COHEN, Washington Crossing, PA;
Gopi VENKATESH, Vandalia, OH;

Dr. Falk Pharma v. Ellodi Pharmaceuticals
IPR2025-00055
Dr. Falk Pharma Ex. 1128

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

OK TO ENTER: /A.S./

09/18/2016

Attorney Docket No. ADAR-119/02US 325049-2959

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 3674
et al.

Application No.: 14/294,660 Group Art Unit: 1615

Filed: June 03, 2014 Examiner: Aradhana SASAN

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. § 1.312

Entry of the following amendment is respectfully requested.

Amendments to the Specification begin on page **2** of this paper.

Remarks begin on page **3** of this paper.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	06/03/2014	Stephen PERRETT	ADAR-119/02US 325049-2959	3674
91543	7590	09/21/2016	EXAMINER	
Cooley LLP ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			09/21/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zpatdcdocketing@cooley.com

Response to Rule 312 Communication	Application No. 14/294,660	Applicant(s) PERRETT ET AL.
	Examiner ARADHANA SASAN	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The amendment filed on 15 September 2016 under 37 CFR 1.312 has been considered, and has been:

- a) ☒ entered.
- b) ☐ entered as directed to matters of form not affecting the scope of the invention.
- c) ☐ disapproved because the amendment was filed after the payment of the issue fee.

Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

- d) ☐ disapproved. See explanation below.
- e) ☐ entered in part. See explanation below.

	/ARADHANA SASAN/ Primary Examiner, Art Unit 1615
--	---

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

91543 7590 06/17/2016
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	06/03/2014	Stephen PERRETT	ADAR-119/02US 325049-2959	3674

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	09/19/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
SASAN, ARADHANA	1615	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 COOLEY LLP

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

ADARE PHARMACEUTICALS, INC.

LAWRENCEVILLE, NEW JERSEY

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-1283 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Jonathan M. Cousin/

Date September 16, 2016

Typed or printed name Jonathan M. Cousin

Registration No. 66,418

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 3674
et al.

Application No.: 14/294,660 Group Art Unit: 1615

Filed: June 03, 2014 Examiner: Aradhana SASAN

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. § 1.312

Entry of the following amendment is respectfully requested.

Amendments to the Specification begin on page **2** of this paper.

Remarks begin on page **3** of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph beginning on page 1, line 3 with the following amended paragraph. The amendments are indicated by underlining.

The present application is a continuation application of U.S. Patent Application Serial No. 12/896,005, filed October 1, 2010, and claims priority to U.S. Provisional Application No. 61,247,642, filed October 1, 2009, the disclosure of which is herein incorporated by reference in its entirety for all purposes.

REMARKS

The specification has been amended to reflect the continuity in the ADS filed on June 3, 2014. Entry and consideration of this amendment is respectfully requested. No new matter is believed to have been added by way of this amendment.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: September 15, 2016

Customer No. 58249

Respectfully submitted,

COOLEY LLP

COOLEY LLP

Attn: Patent Group

1299 Pennsylvania Avenue NW, Suite 700

Washington, DC 20004

Tel: (202) 842-7800

Fax: (202) 842-7899

By: /Raymond Parker/

Raymond Parker, Ph.D.

Reg. No. 34,893

Electronic Acknowledgement Receipt

EFS ID:	26933798
Application Number:	14294660
International Application Number:	
Confirmation Number:	3674
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	91543
Filer:	Jonathan M. Cousin/zainab ariyibi
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/02US 325049-2959
Receipt Date:	15-SEP-2016
Filing Date:	03-JUN-2014
Time Stamp:	16:47:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	ADAR11902US_Comments_SR A.pdf	74899	no	2
			b7c02934f6430161f24c535a6517d55c3e8d c513		

Warnings:

Information:					
2	Amendment after Notice of Allowance (Rule 312)	ADAR11902US_312Amendmen t_.pdf	97548	no	3
			d6cc5150f6f8ce9e604a4d633bd08e94202a d8d7		
Warnings:					
Information:					
Total Files Size (in bytes):				172447	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 3674
et al.

Application No.: 14/294,660 Group Art Unit: 1615

Filed: June 03, 2014 Examiner: Aradhana SASAN

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

In response to the Reasons for Allowance in the Notice of Allowance dated June 17, 2016, the following comments are submitted under 37 C.F.R. 1.104(e).

While the Applicants believe that the claims are allowable and patentably distinguish over the prior art, Applicants do not acquiesce that patentability resides in each feature, exactly as expressed in the claims, nor that each and every feature is required for patentability. Applicants submit that patentability is based on the claimed invention as a whole, and not solely on one or more particular features recited in the allowed claims.

CONCLUSION

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: September 15, 2016

Customer No. 58249

Respectfully submitted,

COOLEY LLP

COOLEY LLP

Attn: Patent Group

1299 Pennsylvania Avenue NW, Suite 700

Washington, DC 20004

Tel: (202) 842-7800

Fax: (202) 842-7899

By: /Raymond Parker/

Raymond Parker, Ph.D.

Reg. No. 34,893



UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

91543 7590 06/17/2016
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

EXAMINER

SASAN, ARADHANA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/17/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/294,660

06/03/2014

Stephen PERRETT

ADAR-119/02US
325049-2959

3674

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	09/19/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

91543 7590 06/17/2016
Cooley LLP
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	06/03/2014	Stephen PERRETT	ADAR-119/02US 325049-2959	3674

TITLE OF INVENTION: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	09/19/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
SASAN, ARADHANA	1615	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

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NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	06/03/2014	Stephen PERRETT	ADAR-119/02US 325049-2959	3674
91543	7590	06/17/2016	EXAMINER	
Cooley LLP			SASAN, ARADHANA	
ATTN: Patent Group			ART UNIT	PAPER NUMBER
1299 Pennsylvania Avenue, Suite 700			1615	
Washington, DC 20004			DATE MAILED: 06/17/2016	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/294,660	Applicant(s) PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment, Remarks and Terminal Disclaimer filed on 05/24/16.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 57-98. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. ☐ Notice of References Cited (PTO-892) | 5. ☐ Examiner's Amendment/Comment |
| 2. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. ☒ Examiner's Statement of Reasons for Allowance |
| 3. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. ☐ Other _____. |
| 4. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____. | |

/ARADHANA SASAN/
Primary Examiner, Art Unit 1615

DETAILED ACTION

Notice of Pre-AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Application

2. Claims 57, 89 and 90 were amended.
3. Claims 57-98 are pending.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance:

Claim Objection

5. In light of the amendment of claim 57, the objection with respect to this claim is withdrawn.

Claim Rejections - 35 USC § 112

6. In light of the amendment of claims 57 and 89, the rejection of these claims under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite, is withdrawn.

Terminal Disclaimer

7. The terminal disclaimer filed on 05/24/16 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent Number 8,771,729 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Updated Search

8. An updated prior art search did not disclose a reference that teaches the limitations of a method of treating an inflammatory condition, including the disintegration within 60 seconds and no significant glucocorticoid or mineralocorticoid activity after oral administration, as recited in the instant claims.

Therefore, the claimed invention is novel and unobvious over the prior art of record.

Comments

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. Claims **57-98** are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Friday from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent

Art Unit: 1615

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aradhana Sasan/
Primary Examiner, Art Unit 1615

Issue Classification 	Application/Control No. 14294660	Applicant(s)/Patent Under Reexamination PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	

CPC						
Symbol					Type	Version
A61K		9		0053	F	2013-01-01
A61K		9		0056	I	2013-01-01
A61K		9		006	I	2013-01-01
A61K		9		0065	I	2013-01-01
A61K		9		06	A	2013-01-01
A61K		31		569	I	2013-01-01
A61K		45		06	I	2013-01-01
A61K		31		56	I	2013-01-01

CPC Combination Sets						
Symbol					Type	Set
					Ranking	Version
A61K		31		569	I	1
A61K		2300		00	A	1

NONE		Total Claims Allowed:	
(Assistant Examiner)		42	
(Date)			
/ARADHANA SASAN/ Primary Examiner.Art Unit 1615		06/10/2016	O.G. Print Claim(s)
(Primary Examiner)		(Date)	O.G. Print Figure
		1	NONE

Issue Classification 	Application/Control No. 14294660	Applicant(s)/Patent Under Reexamination PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION										
CLASS			SUBCLASS			CLAIMED					NON-CLAIMED					
						A	6	1	K	9 / 00 (2006.0)						
CROSS REFERENCE(S)						A	6	1	K	31 / 56 (2006.0)						
						A	6	1	K	45 / 06 (2006.0)						
						A	6	1	K	31 / 569 (2006.0)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					A	6	1	K	9 / 06 (2006.01.01)						

NONE		Total Claims Allowed:	
		42	
(Assistant Examiner)	(Date)		
/ARADHANA SASAN/ Primary Examiner.Art Unit 1615	06/10/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification 	Application/Control No. 14294660	Applicant(s)/Patent Under Reexamination PERRETT ET AL.
	Examiner ARADHANA SASAN	Art Unit 1615

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17		33		49	9	65	25	81	41	97		
	2		18		34		50	10	66	26	82	42	98		
	3		19		35		51	11	67	27	83				
	4		20		36		52	12	68	28	84				
	5		21		37		53	13	69	29	85				
	6		22		38		54	14	70	30	86				
	7		23		39		55	15	71	31	87				
	8		24		40		56	16	72	32	88				
	9		25		41	1	57	17	73	33	89				
	10		26		42	2	58	18	74	34	90				
	11		27		43	3	59	19	75	35	91				
	12		28		44	4	60	20	76	36	92				
	13		29		45	5	61	21	77	37	93				
	14		30		46	6	62	22	78	38	94				
	15		31		47	7	63	23	79	39	95				
	16		32		48	8	64	24	80	40	96				

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 42	
/ARADHANA SASAN/ Primary Examiner.Art Unit 1615 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure NONE

Application Number 	Application/Control No. 14/294,660	Applicant(s)/Patent under Reexamination PERRETT ET AL.	
Document Code - DISQ		Internal Document – DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 5/24/16	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
jean proctor

U.S. Patent and Trademark Office

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)

ADAR-119/02US 325049-2959

In re Application of: PERRETT, Stephen, et al.

Application No.: 14/294,660

Filed: June 3, 2014

For: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

The owner*, Adare Pharmaceuticals, Inc., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 8,771,729 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 34,893

/Raymond S. Parker, III/May 24, 2016

Signature

Date

Raymond S. Parker

Typed or printed name

202-842-7800

Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:		14294660		
Filing Date:		03-Jun-2014		
Title of Invention:		ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
First Named Inventor/Applicant Name:		Stephen PERRETT		
Filer:		Raymond Samuel Parker/zainab ariyibi		
Attorney Docket Number:		ADAR-119/02US 325049-2959		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	1	160	160
Total in USD (\$)				160

Electronic Acknowledgement Receipt

EFS ID:	25866645
Application Number:	14294660
International Application Number:	
Confirmation Number:	3674
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	91543
Filer:	Raymond Samuel Parker/zainab ariyibi
Filer Authorized By:	Raymond Samuel Parker
Attorney Docket Number:	ADAR-119/02US 325049-2959
Receipt Date:	24-MAY-2016
Filing Date:	03-JUN-2014
Time Stamp:	13:47:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	41
Deposit Account	501283
Authorized User	COOLEY LLP

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	ADAR11902US_RespOA.pdf	156302	no	12
			1c33d26709c5b71e7491f6be1143a6db2e6efe94		
Warnings:					
Information:					
2	Terminal Disclaimer Filed	ADAR11902US_TD.pdf	157152	no	2
			864a6d8f7963d38eef843ae9025c4e08f9b82a42		
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	Abstract_JP_2009173552_.pdf	733595	no	2
			315e78d1d291c1c50986b755571f0cd35be93d62		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30567	no	2
			03b2979209460ac35a89933c8db6dfa328f5b90b		
Warnings:					
Information:					
Total Files Size (in bytes):			1077616		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 3674
et al.

Application No.: 14/294,660 Group Art Unit: 1615

Filed: June 03, 2014 Examiner: Aradhana SASAN

FOR: **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

Filed Via EFS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY UNDER 37 C.F.R. § 1.111

This paper is a response to the Office Action mailed on February 26, 2016. Applicants respectfully request reconsideration of the above-identified application in view of the following remarks and amendments to the claims. This reply is filed within three months of the shortened statutory period set for reply in the Office Action mailed on February 26, 2015. Accordingly, it is believed that no extension of time fees are due. However, should the United States Patent and Trademark Office determine that any additional fee is required or a refund is owed for this application, the Commission is hereby authorized and requested to charge any fees deemed necessary and/or credit any refund owed to our Deposit Account 50-1283.

Claim Amendments begin on page 2 of this paper;

Remarks begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

The following Listing of Claims will replace all prior versions and Listings of Claims in the application.

Listing of Claims:

1.-56. (Cancelled).

57. (Currently Amended) A method of treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition comprising less than or equal to 20 mg of a topically administrable corticosteroid and at least one excipient, wherein:
the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,
the ~~solid~~ pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.
58. (Previously Presented) The method of claim 57, wherein said pharmaceutical composition disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.
59. (Previously Presented) The method of claim 57, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.
60. (Previously Presented) The method of claim 57, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).
61. (Previously Presented) The method of claim 60, wherein the ODT comprises drug particles and rapidly dispersing granules, the drug particles comprise the corticosteroid, the rapidly dispersing granules comprise a disintegrant, the excipient is a sugar alcohol, a

saccharide, or a mixture thereof, and the drug particles are disposed over the surface of the rapidly dispersing granules.

62. (Previously Presented) The method of claim 61, wherein the drug particles have an average particle size of less than about 400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and the sugar alcohol, the saccharide, or mixture thereof have an average particle size of less than about 30 μm .
63. (Previously Presented) The method of claim 61, wherein the drug particles have an average particle size of less than about 4 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol, the saccharide, or mixture thereof have an average particle size of less than about 30 μm .
64. (Previously Presented) The method of claim 61, wherein the corticosteroid is disposed over the surface of the excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and the sugar alcohol, the saccharide, or mixture thereof have an average particle size of less than about 30 μm .
65. (Previously Presented) The method of claim 61, wherein the ODT further comprises microcrystalline cellulose and a pharmaceutically acceptable sweetener, flavorant, and/or colorant, and wherein the excipient is the sugar alcohol.
66. (Previously Presented) The method of claim 61, wherein the sugar alcohol is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, and combinations thereof.
67. (Previously Presented) The method of claim 61, wherein the saccharide is selected from the group consisting of lactose, sucrose, maltose, and combinations thereof.
68. (Previously Presented) The method of claim 61, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked

carboxymethyl cellulose, low-substituted hydroxypropylcellulose, and combinations thereof.

69. (Previously Presented) The method of claim 65, wherein the sugar alcohol is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, and combinations thereof.
70. (Previously Presented) The method of claim 65, wherein the saccharide is selected from the group consisting of lactose, sucrose, maltose, and combinations thereof.
71. (Previously Presented) The method of claim 65, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, and combinations thereof.
72. (Previously Presented) The method of claim 57, further comprising an adhesive agent.
73. (Previously Presented) The method of claim 72, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gums, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.
74. (Previously Presented) The method of claim 57, further comprising a disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

75. (Previously Presented) The method of claim 57, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.
76. (Previously Presented) The method of claim 57, wherein the orally disintegrating solid pharmaceutical composition is substantially free of lubricant.
77. (Previously Presented) The method of claim 72, wherein the adhesive agent and the corticosteroid are intimately associated.
78. (Previously Presented) The method of claim 77, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.
79. (Previously Presented) The method of claim 77, wherein the corticosteroid is disposed on the surface of said adhesive agent.
80. (Previously Presented) The method of claim 60, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.
81. (Previously Presented) The method of claim 80, wherein the ODT is in the form of a wafer or film.
82. (Previously Presented) The method of claim 61, wherein the ODT is in the form of a wafer or film.
83. (Previously Presented) The method of claim 57, further comprising at least one antifungal agent.
84. (Previously Presented) The method of claim 83, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.

85. (Previously Presented) The method of claim 84, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.
86. (Previously Presented) The method of claim 57, further comprising at least one antiviral agent.
87. (Previously Presented) The method of claim 86, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, purine analogs, pyrimidine analogs, and uncategorized antiviral drugs.
88. (Previously Presented) The method of claim 87, wherein the antiviral agent is selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclovir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.
89. (Currently Amended) The method of claim ~~59~~ 60, wherein the orally disintegrating tablet comprises about 0.01 to about 20 mg fluticasone.
90. (Currently Amended) The method of claim ~~90~~ 60, wherein the orally disintegrating tablet comprises about 0.05-3.0 mg fluticasone.
91. (Previously Presented) An orally disintegrating solid pharmaceutical composition comprising less than or equal to about 20 mg of a topically administrable corticosteroid and at least one excipient,
wherein:
the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,
wherein the solid pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.

92. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, wherein said orally disintegrating solid pharmaceutical composition disintegrates within 30 seconds.
93. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.
94. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, further comprising an adhesive agent.
95. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.
96. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, further comprising at least one antifungal agent.
97. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, further comprising at least one antiviral agent.
98. (Previously Presented) The orally disintegrating solid pharmaceutical composition of claim 91, wherein the orally disintegrating tablet comprises about 0.01 to about 20 mg fluticasone.

REMARKS

I. Status of the Claims

The Examiner has withdrawn the restriction requirement of 5/18/15. Accordingly, the status identifiers of claims 91-98 have been changed from “withdrawn” to “previously presented.” Therefore, after entry of this amendment, claims 57-98 are currently pending.

Claim 57 was amended to remove the term “solid” from line 8 of the claim.

Claim 89 was amended to depend on claim 60, rather than claim 59.

Claim 90 was amended to depend on 60, rather than claim 90.

No new matter is believed to have been added by these amendments.

II. Claim Rejections under 35 U.S.C. § 112

The Examiner rejected claim 57 under 35 U.S.C. § 112, alleging that “[c]laim 57 recites the limitation ‘*the solid pharmaceutical composition*’ in line 8. However, the preceding portion of claim 57 does not recite the term ‘*solid*’ with respect to the pharmaceutical composition.” Claim 57 is amended herein to cancel the term “*solid*” from line 8, such that line 8 of currently amended claim 57 properly refers to “*the pharmaceutical composition*” of the preceding portion of claim 57. Accordingly, Applicants respectfully request withdrawal and reconsideration of the rejection.

The Examiner rejected claim 89 under 35 U.S.C. § 112, alleging that an “*orally disintegrating tablet*” is not recited in claims 59 or 57 upon which claim 89 depends. Claim 89 is amended herein to depend on claim 60, which recites “*an orally disintegrating tablet (ODT)*.” Therefore, Applicants’ submit that claim 60 provides an antecedent basis for “*the orally disintegrating tablet*” in currently amended claim 89. Accordingly, Applicants respectfully request withdrawal and reconsideration of the rejection.

III. Terminal Disclaimer

Claims 57-98 are rejected on the ground of nonstatutory double patenting over claims 1-40 of U.S. Patent No. 8,771,729. Without acquiescing to the propriety of these rejections, submitted herewith is a terminal disclaimer over U.S. Patent No. 8,771,729.

IV. Comments on Notice of Allowance in Related U.S. Application No. 14/311,732

In the Notice of Allowance received in the corresponding case, U.S. App. No. 14/311,732, the Examiner indicated that “several documents from the IDS filed on 9/28/15 and 12/17/15 were not provided.” Applicants note that the IDS filed on 9/28/15 in corresponding U.S. App. No. 14/311,732 included references which were disclosed in the above-referenced application in the IDS filed on 10/7/15, and the IDS filed on 12/17/15 in corresponding U.S. App. No. 14/311,732 is similar to the IDS filed on 12/17/15 in the above-referenced application. Applicants respectfully disagree with the Examiner’s allegation that “several documents were not provided” and, for consistency, will address the Examiner’s comments in the present application as well in the Comments on the Notice of Allowance to be filed in corresponding U.S. App. No. 14/311,732.

- Foreign Patent Document JP 2009173552 was cited by a Japanese Examiner against a predecessor application, which corresponds to U.S. Patent No. 8,771,729. There is no English version of a published application which corresponds to JP 2009173552. However, provided herewith is a machine translation of the abstract of JP 2009173552 obtained from Escapenet. The machine translation indicates that JP 2009173552 is directed to an intraoral disintegrating tablet containing sucralfate. Said machine translated abstract can also be viewed with the following link:
http://worldwide.espacenet.com/publicationDetails/biblio?II=1&ND=3&adjacent=true&locale=en_EP&FT=D&date=20090806&CC=JP&NR=2009173552A&KC=A.
- Foreign Patent Document JP 2003-509359 corresponds to Foreign Patent Document WO 2001/01934, which was provided with the Information Disclosure Statement filed on December 17, 2015.

- Foreign Patent Document JP 2003-292459 corresponds to U.S. Patent Application Publication 2004/0009212, which was provided with the Information Disclosure Statement filed on December 17, 2015.
- Foreign Patent Document JP H11-130679 corresponds to U.S. Patent Application Publication 2001/0006625, which was provided with the Information Disclosure Statement filed on December 17, 2015.
- NPL Nos. 1 and 3-5 (IDS filed on December 17, 2015) are English Translations of foreign office actions, and the references cited in these foreign office actions were disclosed in an IDS as set forth below.
 - The references cited in NPL No. 1 are as follows:
 - WO 2009-064819, corresponding to Foreign Patent Document entry 1 in the IDS filed on December 17, 2015;
 - JP 2003-509359, corresponding to Foreign Patent Document entry 2 in the IDS filed on December 17, 2015;
 - JP 2003-292459, corresponding to Foreign Patent Document entry 3 in the IDS filed on December 17, 2015;
 - JP H11-130679, corresponding to Foreign Patent Document entry 4 in the IDS filed on December 17, 2015; and
 - Kumari, et al. Indian J. Otolaryngol. Head Neck Surg. 2008, Vol. 60, No., 3, p. 199-201, corresponding to NPL entry 2 in the IDS filed on December 17, 2015.
 - The references cited in NPL No. 3 are as follows:
 - US 2009/0149433, which was previously disclosed in the IDS filed on March 31, 2015 as U.S. Patent Application Publication entry 9;
 - US 2009/0123551, which was previously disclosed in the IDS filed on October 7, 2015 as U.S. Patent Application Publication entry 2;
 - US 4,080,448, which was cited by Examiner Sasan against U.S. App. No. 14/311,732 in the Notice of References Cited dated June 4, 2015;

- US 4,363,806, which was cited by Examiner Sasan against U.S. App. No. 14/311,732 in the Notice of References Cited dated June 4, 2015;
- US 5,135,740, which was cited by Examiner Sasan against U.S. App. No. 14/311,732 the Notice of References Cited dated June 4, 2015;
- US 5,776,433, which was cited by Examiner Sasan against U.S. App. No. 14/311,732 in the Notice of References Cited dated June 4, 2015; and
- US 2009/0123550, which was cited by Examiner Sasan against U.S. App. No. 14/311,732 in the Notice of References Cited dated June 4, 2015.
- The references cited in NPL No. 4 are as follows:
 - US 2009/0149433, which was previously disclosed in the IDS filed on March 31, 2015 as U.S. Patent Application Publication entry 9; and
 - US 2009/0123551, which was previously disclosed in the IDS filed on October 7, 2015 as U.S. Patent Application Publication entry 2.
- The references cited in NPL No. 5 are as follows:
 - US 2003/0054036, which is U.S. Patent Application Publication entry 1 in the IDS filed on February 11, 2015;
 - WO 2005/087194, which was disclosed as Foreign Patent Document entry 1 in the IDS filed on December 29, 2015. The Examiner's attention is directed to the typographical error in the publication number, which indicates that the reference is WO 2003/087194, instead of correctly identifying the reference as WO 2005/087194; and
 - WO 2008/098634, which was disclosed as Foreign Patent Document entry 2 in the IDS filed on December 29, 2015.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon. The Examiner is invited to contact the undersigned if any additional information is required.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.13634(a)(3).

Dated: May 24, 2016
Customer No. 58249

Respectfully submitted,
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Raymond S. Parker, III
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Exhibits

- Machine translation of abstract of JP 2009173552

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/294,660	Filing Date 06/03/2014	☐ To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	05/24/2016	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 42	Minus	** 54	= 0	x \$80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	x \$420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/GLORIA NORRIS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	06/03/2014	Stephen PERRETT	ADAR-119/02US 325049-2959	3674
91543	7590	02/26/2016	EXAMINER	
Cooley LLP ATTN: Patent Group 1299 Pennsylvania Avenue, Suite 700 Washington, DC 20004			SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			02/26/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zpatdcdocketing@cooley.com

Office Action Summary	Application No. 14/294,660	Applicant(s) PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/20/15.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 57-98 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 57-98 is/are rejected.
- 8) ☒ Claim(s) 90 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

DETAILED ACTION

Notice of Pre-AIA or AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

2. Applicants' election without traverse of Group II (claims 29-34) in the reply filed on 07/13/15 is acknowledged.
3. On 11/20/15 Applicants cancelled claims 1-56 and added new claims 57-98. Applicants' remarks filed on 11/20/15 are acknowledged. Upon further consideration and in light of the amendment and the remarks of 11/20/15, which relate to methods and compositions claimed in parent case (SN: 12/896,005 – which is now U.S. Patent No. 8,771,729), the restriction requirement of 05/18/15 has been withdrawn.
4. Claims 57-98 are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statements (IDS) filed on 06/03/14, 09/05/14, 10/01/14, 11/17/14, 02/11/15, 03/31/15, 05/21/15, 05/29/15, 06/11/15, 10/07/15, 10/27/15, 12/17/15 and 12/29/15 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements. See attached copies of PTO-1449.

Claim Objections

6. Claim **90** is objected to under 37 CFR 1.75(c) as being in improper form because it is dependent on itself. See MPEP § 608.01(n). Since claim 90 recites the limitation of

an “orally disintegrating tablet,” it is construed to be dependent on claim 60. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims **57** and **89** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

- i. Claim **57** recites the limitation “the solid pharmaceutical composition” in line 8. However, the preceding portion of claim 57 does not recite the term “solid” with respect to the pharmaceutical composition. There is insufficient antecedent basis for this limitation in the claim.
- ii. Claim **89** recites the limitation “wherein the orally disintegrating tablet” in line 1. Claim 89 is dependent on claim 59, and ultimately dependent on claim 57. However, neither claim 59 nor claim 57 recite an “orally disintegrating tablet.” There is insufficient antecedent basis for this limitation in the claim. The limitation of “an orally disintegrating tablet” is recited in claim 60. It is recommended that claim 89 be dependent on claim 60.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

10. Claims 57-98 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 8,771,729 B2 (the '729 Patent).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to an orally disintegrating solid pharmaceutical composition comprising less than or equal to about 20 mg of a topically administrable corticosteroid and a method of treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof the pharmaceutical composition.

The difference is that claims of the '729 Patent recite specifically that the orally disintegrating solid pharmaceutical composition which comprises less than or equal to about 20 mg of a topically administrable corticosteroid contains at least one

disintegrant, whereas instant claims recite that "at least one excipient" is combined with the topically administrable corticosteroid. However, one of ordinary skill in the art would know that the disintegrant of the '729 Patent is a species of the genus "excipient" and therefore anticipates and renders obvious the instant claims.

Therefore, instant claims are obvious over claims of the '729 Patent and they are not patentably distinct over each other.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aradhana Sasan/
Primary Examiner, Art Unit 1615

REMARKS**I. Status of the Claims**

The Notice of Non-Compliant Amendment issued in the above-identified application indicates that withdrawn claims 1-28 and 55-56 “must be cited.”

Applicants submit herewith a listing of claims in compliance with 37 C.F.R. § 1.121(c). Applicants note that Claims 1-56 have now been cancelled, and new claims 57-98 have been added. Accordingly, the status identifiers of these claims have been updated as “canceled” and “new” rather than “withdrawn.” As there is no requirement that the text of canceled claims be recited in a response, Applicants submit that the present listing of claims and status modifiers are in compliance with the relevant USPTO rules.

New independent claim 57 is similar to claim 29 allowed in U.S. Patent No. 8,771,729, and new independent claim 91 is similar to claim 1 allowed in U.S. Patent No. 8,771,729, except that “disintegrant” is replaced with “excipient.” This change is supported throughout the originally filed specification. Thus, no new matter is believed to be added.

Lastly, new dependent claims are added in the claim listing submitted herewith which further define the method and solid pharmaceutical composition. The limitations recited in the new dependent claims are supported throughout the specification and in the original claims as filed. No new matter is believed to be added.

Because the present application relates to methods and compositions for which claims have previously been allowed (U.S. Patent No. 8,771,729), and the presently pending claims differ *inter alia* by the replacement of “disintegrant” with “excipient,” Applicants respectfully submit that the present claims are in condition for allowance and request favorable action thereon.

II. Amendments to the Specification

Typographical errors in the originally filed Specification of the parent application (U.S. Patent Application No. 12/896,005) regarding the correction of “alignate” to “alginat” and “puridine” to “purine” were corrected via amendments submitted therein. The same errors are present in this divisional application and are corrected by the amendments submitted herewith. In addition “Eudragit®” has been replaced with “EUDRAGIT®.”

An obvious error in the originally filed Specification of the parent application (U.S. Patent Application No. 12/896,005) regarding the USP <701> Disintegration Test was discovered and was subsequently corrected via an amendment submitted therein. The same obvious error is present in this divisional application and is corrected by the amendment submitted herewith.

It is well known that the USP <701> Disintegration Test is run in the presence of water rather than simulated saliva. See Appendix 1 (*The United States Pharmacopeial Convention*, <701 Disintegration >, August 1, 2008 and comments from the USP website regarding the same). However, at three locations in the Specification, “simulated saliva” is mistakenly referred to as the testing medium. This is corrected herein by amendment.

No new matter is added by these amendments per M.P.E.P. § 2163(I)(B) (“An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.”) (internal citation omitted). Entry of the amendment is respectfully requested.

In the specification, the terms, “ingredient” and “excipient” are used interchangeably. However, the applicants wish to amend the affected paragraphs by replacing “ingredient” with “excipient” for consistency and to make the application unambiguous.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon. The Examiner is invited to contact the undersigned if any additional information is required.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: November 20, 2015

Customer No. 58249

Respectfully submitted,

COOLEY LLP

COOLEY LLP

Attn: Patent Group

1299 Pennsylvania Avenue NW, Suite 700

Washington, DC 20004

Tel: (202) 728-7079

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By: **/Thomas A. Blinka/**

Thomas A. Blinka, Ph.D.

Reg. No. 44,541

Electronic Patent Application Fee Transmittal				
Application Number:		14294660		
Filing Date:		03-Jun-2014		
Title of Invention:		ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
First Named Inventor/Applicant Name:		Stephen PERRETT		
Filer:		Jonathan M. Cousin/Vanessa Jones		
Attorney Docket Number:		ADAR-119/02US 325049-2959		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 2 months with \$0 paid	1252	1	600	600
Miscellaneous:				
Total in USD (\$)				600

Electronic Acknowledgement Receipt

EFS ID:	24144634
Application Number:	14294660
International Application Number:	
Confirmation Number:	3674
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	91543
Filer:	Jonathan M. Cousin/Vanessa Jones
Filer Authorized By:	Jonathan M. Cousin
Attorney Docket Number:	ADAR-119/02US 325049-2959
Receipt Date:	20-NOV-2015
Filing Date:	03-JUN-2014
Time Stamp:	12:55:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$600
RAM confirmation Number	12540
Deposit Account	501283
Authorized User	COOLEY LLP

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ADAR-119_02US_Response_Noncompliant_Amendment.pdf	148469 d7256ac3567c5d294a5044db7a7367b3fc77e963	yes	14

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Arguments/Remarks Made in an Amendment		1	1	
	Specification		2	5	
	Claims		6	11	
	Amendment/Req. Reconsideration-After Non-Final Reject		12	14	

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30609 3c194db3cd95c02684eb9c4804eae490670f9c6f	no	2
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Warnings:

Information:

Total Files Size (in bytes):			179078
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: PERRETT, Stephen, Confirmation No.: 3674
et al.

Application No.: 14/294,660 Group Art Unit: 1615

Filed: June 03, 2014 Examiner: Aradhana SASAN

FOR: ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

Filed Via EFS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

RESPONSE TO NON-COMPLIANT AMENDMENT (37 C.F.R. § 1.121)

This paper is filed in response to the Notice of Non-Compliant Amendment (37 C.F.R. § 1.121) dated July 21, 2015. The shortened statutory period expired September 21, 2015. Filed herewith is an extension of time to extend the period for reply to November 21, 2015. Accordingly, the response is timely filed. Applicants submit herewith a listing of claims in compliance with 37 C.F.R. § 1.121.

Amendments to the Specifications begin on page **2** of this paper;

Claim Amendments begin on page **6** of this paper;

Remarks begin on page **12** of this paper

IN THE SPECIFICATION:

Please replace the paragraph beginning on page 2, line 8 with the following amended paragraph. The amendments are indicated by strikethrough.

In one embodiment, the present invention is directed to a solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralcorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds ~~in simulated saliva~~ when tested using the USP <701> Disintegration Test, and/or which disintegrates within 60 seconds when placed in the oral cavity of a human.

Please replace the paragraph beginning on page 7, line 3 with the following amended paragraph. The amendments are indicated by strikethrough.

In one embodiment, the present invention provides a solid pharmaceutical composition which comprises less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity, and wherein the solid pharmaceutical composition disintegrates within 60 seconds ~~in simulated saliva~~ when tested using the USP <701> Disintegration Test. In another embodiment, the solid pharmaceutical compositions of the present invention disintegrate within 60 seconds in the oral cavity of the patient, e.g., human. In still other embodiments, the solid pharmaceutical compositions of the present invention disintegrate within 30 seconds ~~in simulated saliva~~ (using the USP <701> Disintegration Test), or in the oral cavity of a patient. In still other embodiments, the solid or liquid pharmaceutical compositions of the present invention topically provide a therapeutically effective amount of a corticosteroid to inflamed tissues of the gastrointestinal tract, after oral administration to a patient in need thereof.

Please replace the paragraph beginning on page 15, line 10 with the following amended paragraph. The amendments are indicated by strikethrough and/or underlining.

In one embodiment, the solid pharmaceutical compositions of the present invention include an adhesive agent. Suitable adhesive agents include sucrose aluminum sulfate complex, chitosan and derivatives thereof (e.g., trimethylchitosan, chitosan salts), polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, EUDRAGIT[®] polymers (E, L, S, NE, RL, and RS grades), carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked ~~alginate~~ alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

Please replace the paragraph beginning on page 16, line 16 with the following amended paragraph. The amendments are indicated by strikethrough and/or underlining.

In another embodiment, pharmaceutical compositions of the present invention include an antiviral agent. Antiviral agents which may be included in the solid pharmaceutical compositions of the present invention include interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, guanosine analogs, ~~puridine~~ purine analogs, pyrimidine analogs, and other "uncategorized" antiviral drugs recognized in the art which do not fall within any of the above classes (e.g. foscarnet and miltefosine). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abacavir, aciclovir (also known as acyclovir), adefovir, amantadine, amdoxovir, amprenavir, aplaviroc, apricitabine, arbidol, atazanavir, bevirimat, BMS-488043, boceprevir, brivudine, cidofovir, DCM205, docosanol, delavirdine, didanosine, durunavir, efavirenz, elvitegravir, elvucitabine, emtricitabine, enfuvirtide, epigallocatechin gallate,

etravirine, famciclovir, fosamprenavir, ganciclovir, globoidnan A, griffithsin, ibalizumab, idoxuridine, indinavir, lamivudine, lopinavir, loviride, maraviroc, nelfinavir, nevirapine, oseltamivir, pegylated interferon α -2a, pegylated interferon α -2b, penciclovir, peramivir, plerixafor, PRO 140, racivir, raltegravir, ritonavir, ribavirin, rimantadine, rilpivirine, saquinavir, stampidine, stavudine, tenofovir, tipranavir, TNX-355, trifluridine, tromantadine, valaciclovir, valganciclovir, vicriviroc, vidarabione, viramidine, vivecon, zalcitabine, zanamivir, and zidovudine.

Please replace the paragraph beginning on page 3, line 14 with the following amended paragraph. The amendments are indicated by strikethrough and underlining.

The terms "orally disintegrating tablet", "orally dispersing tablet", or "ODT" refer to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing. The rate of oral disintegration can vary, but is significantly faster than the rate of oral disintegration of conventional solid dosage forms or chewable solid dosage forms (i.e., tablets or capsules) which are intended to be swallowed immediately after administration. ODT compositions of the present invention can contain pharmaceutically acceptable excipients ~~ingredients~~ which swell, dissolve or otherwise ~~facilitating~~ facilitate the disintegration or dissolution of the ODT composition. Such excipients ~~ingredients~~ can include ~~pharmaceutical~~ a disintegrant, a sugar alcohol, a saccharide, or a mixture thereof, a water-soluble binder, a melttable solid (e.g., a wax), which can release the corticosteroid upon entering the stomach, etc.

Please replace the paragraph beginning on page 18, line 8 with the following amended paragraph. The amendments are indicated by strikethrough and underlining.

The corticosteroid-containing granules of the present invention may also include other pharmaceutically acceptable excipients ~~ingredients~~, for example, fillers or diluents. Non-limiting examples of other pharmaceutically acceptable excipients ~~ingredients~~ for the corticosteroid-containing granules include, for example, mannitol, lactose, microcrystalline cellulose, potassium sulfate, calcium phosphate, modified starch, and mixtures thereof. The amount of other pharmaceutically acceptable ingredients (e.g. fillers or diluents) in the corticosteroid-

containing granules can range from about 5%-80%, including about 5%-70%, about 5%-60%, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, about 5%-15%, about 5%-10%, about 10%-70%, about 10%-60%, about 10%-50%, about 10%-40%, about 10%-30%, about 10%-20%, about 10%-15%, about 20%-70%, about 20%-60%, about 20%-50%, about 20%-40%, about 20%-30%, about 20%-25%, about 30%-70%, about 30%-60%, about 30%-50%, about 30%-40%, about 30%-35%, about 40%-70%, about 40%-60%, about 40%-50%, about 40%-45%, about 50%-70%, about 50%-60%, about 50%-55%, about 60%-70%, or about 60%-65%.

AMENDMENTS TO THE CLAIMS

The following Listing of Claims will replace all prior versions and Listings of Claims in the application.

Listing of Claims:

1.-56. (Cancelled).

57. (New) A method of treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition comprising less than or equal to 20 mg of a topically administrable corticosteroid and at least one excipient,
wherein:
the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,
the solid pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.
58. (New) The method of claim 57, wherein said pharmaceutical composition disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.
59. (New) The method of claim 57, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.
60. (New) The method of claim 57, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).
61. (New) The method of claim 60, wherein the ODT comprises drug particles and rapidly dispersing granules, the drug particles comprise the corticosteroid, the rapidly dispersing granules comprise a disintegrant, the excipient is a sugar alcohol, a saccharide, or a

mixture thereof, and the drug particles are disposed over the surface of the rapidly dispersing granules.

62. (New) The method of claim 61, wherein the drug particles have an average particle size of less than about 400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and the sugar alcohol, the saccharide, or mixture thereof have an average particle size of less than about 30 μm .
63. (New) The method of claim 61, wherein the drug particles have an average particle size of less than about 4 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol, the saccharide, or mixture thereof have an average particle size of less than about 30 μm .
64. (New) The method of claim 61, wherein the corticosteroid is disposed over the surface of the excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and the sugar alcohol, the saccharide, or mixture thereof have an average particle size of less than about 30 μm .
65. (New) The method of claim 61, wherein the ODT further comprises microcrystalline cellulose and a pharmaceutically acceptable sweetener, flavorant, and/or colorant, and wherein the excipient is the sugar alcohol.
66. (New) The method of claim 61, wherein the sugar alcohol is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, and combinations thereof.
67. (New) The method of claim 61, wherein the saccharide is selected from the group consisting of lactose, sucrose, maltose, and combinations thereof.
68. (New) The method of claim 61, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, and combinations thereof.

69. (New) The method of claim 65, wherein the sugar alcohol is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, and combinations thereof.
70. (New) The method of claim 65, wherein the saccharide is selected from the group consisting of lactose, sucrose, maltose, and combinations thereof.
71. (New) The method of claim 65, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, and combinations thereof.
72. (New) The method of claim 57, further comprising an adhesive agent.
73. (New) The method of claim 72, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gums, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.
74. (New) The method of claim 57, further comprising a disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.
75. (New) The method of claim 57, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.

76. (New) The method of claim 57, wherein the orally disintegrating solid pharmaceutical composition is substantially free of lubricant.
77. (New) The method of claim 72, wherein the adhesive agent and the corticosteroid are intimately associated.
78. (New) The method of claim 77, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.
79. (New) The method of claim 77, wherein the corticosteroid is disposed on the surface of said adhesive agent.
80. (New) The method of claim 60, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.
81. (New) The method of claim 80, wherein the ODT is in the form of a wafer or film.
82. (New) The method of claim 61, wherein the ODT is in the form of a wafer or film.
83. (New) The method of claim 57, further comprising at least one antifungal agent.
84. (New) The method of claim 83, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.
85. (New) The method of claim 84, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.
86. (New) The method of claim 57, further comprising at least one antiviral agent.

87. (New) The method of claim 86, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, purine analogs, pyrimidine analogs, and uncategorized antiviral drugs.
88. (New) The method of claim 87, wherein the antiviral agent is selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclovir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.
89. (New) The method of claim 59, wherein the orally disintegrating tablet comprises about 0.01 to about 20 mg fluticasone.
90. (New) The method of claim 90, wherein the orally disintegrating tablet comprises about 0.05-3.0 mg fluticasone.
91. (New, withdrawn) An orally disintegrating solid pharmaceutical composition comprising less than or equal to about 20 mg of a topically administrable corticosteroid and at least one excipient,
wherein:
the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,
wherein the solid pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.
92. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, wherein said orally disintegrating solid pharmaceutical composition disintegrates within 30 seconds.
93. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, wherein said corticosteroid is selected from the group consisting of budesonide,

fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.

94. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, further comprising an adhesive agent.
95. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.
96. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, further comprising at least one antifungal agent.
97. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, further comprising at least one antiviral agent.
98. (New, withdrawn) The orally disintegrating solid pharmaceutical composition of claim 91, wherein the orally disintegrating tablet comprises about 0.01 to about 20 mg fluticasone.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/294,660	Filing Date 06/03/2014	☐ To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	11/20/2015	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 42	Minus	** 54	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X \$420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/SHAREILL COLES/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office

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www.uspto.gov

100622 e 2015-07-21

Forest Laboratories, Inc.
(c/o Carter, DeLuca, Ferrell & Schmidt, LLP)
445 Broad Hollow Road, Suite 420
Melville, NY 11747

Paper No.

Application No.:	14/294,660 	Date Mailed:	2015-07-21
First Named Inventor:	Stephen PERRETT	Examiner:	SASAN, ARADHANA
Attorney Docket No.:	2240-3 CON	Art Unit:	1615
Confirmation No.:	3674	Filing Date:	06/03/2014

Please find attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 14/294,660	Applicant(s) PERRETT ET AL.
		Art Unit 3600

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

The amendment document filed on 13 July, 2015 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: See Continuation Sheet.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4): For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period if the non-compliant amendment is an** after-final amendment or an amendment filed after allowance, or a drawing submission (only) If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **two months** from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1 to 4 are checked, the correction required is only the corrected section of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable /TARA WASHINGTON/

Telephone No: (571)272-6241

Continuation of 4. Other: Withdrawn claims 1 through 28 along with claims 55, 56 must be cited..

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Stephen Perrett	Examiner:	Aradhana Sasan
Serial No.:	14/294,660	Art Unit:	1615
Filed:	June 3, 2014	Dated:	July 13, 2015
Title:	"ORALLY ADMINISTERED CORTICOSTERIOD COMPOSITIONS".		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Filed Via EFS-Web
Confirmation No.: 3674

RESPONSE TO RESTRICTION REQUIREMENT

Madam:

This is a response to the Office Action mailed May 18, 2015.

Amendments to the Claims begin on page 2 of this Response

Remarks begin on page 3 of this Response.

AMENDMENTS TO CLAIMS

1. through 28. (Withdrawn)

29. (Currently Amended) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test according to claim 1.

30. (Previously Presented) The method of claim 29, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.

31. (Previously Presented) The method of claim 29, wherein said condition is eosinophilic esophagitis.

32. (Previously Presented) The method of claim 29, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.

33. (Previously Presented) The method of claim 29, wherein said condition is viral or bacterial pharyngitis.

34. (Previously Presented) The method of claim 29, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.

35. through 54. (Cancelled)

55. (Withdrawn)

56. (Withdrawn)

REMARKS

This a response to the Office Action mailed May 18, 2015. The Examiner required restriction between Inventions I-II. Invention I includes claims 1-28, 55-56, drawn to a solid pharmaceutical composition and an orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid. Invention II includes claims 29-34, drawn to a method of treating an inflammatory condition of the gastrointestinal tract. Claims 35-54 were previously cancelled.

Applicant elects to prosecute Invention II encompassing claims 29-34 drawn to a method of treating an inflammatory condition of the gastrointestinal tract, without traverse. Applicant affirms its right to pursue the non-elected subject matter in one or more divisional or continuation applications. Applicant also reserves the right to rejoin any non-elected subject matter and the claims.

A good faith effort has been made to place the present application in condition for allowance. Early and favorable consideration of the case is respectfully requested. If there is any issue needing discussion prior to allowance, the Examiner is respectfully requested to telephone the undersigned attorney for applicants at the letterhead address indicated below.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-2140.

Respectfully submitted,

/Sonsy P. Rajan, Reg. #68269/

Sonsy P. Rajan
Reg. No.: 68,269
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road - Suite 420
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

SR:jd

Electronic Acknowledgement Receipt

EFS ID:	22898665
Application Number:	14294660
International Application Number:	
Confirmation Number:	3674
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	100622
Filer:	Thomas Michael Rosselli/Julie Dascoli
Filer Authorized By:	Thomas Michael Rosselli
Attorney Docket Number:	2240-3 CON
Receipt Date:	13-JUL-2015
Filing Date:	03-JUN-2014
Time Stamp:	15:11:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response_to_Restriction_Requ irement_filed_713.PDF	121771 a9b1f12415cce09d02ea1b550f87a6079871 4eb4	yes	3

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Response to Election / Restriction Filed	1	1	
Claims	2	2	
Applicant Arguments/Remarks Made in an Amendment	3	3	

Warnings:

Information:

Total Files Size (in bytes):	121771
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/294,660	Filing Date 06/03/2014	☐ To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

	07/13/2015	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	* 6	Minus	** 54	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X \$420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
	TOTAL ADD'L FEE						0

(Column 1)

(Column 2)

(Column 3)

		CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
	TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/TARA WASHINGTON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/294,660	06/03/2014	Stephen PERRETT	EUR-119/02US	3674

100622 7590 05/18/2015
Forest Laboratories, Inc.
(c/o Carter, DeLuca, Ferrell & Schmidt, LLP)
445 Broad Hollow Road, Suite 420
Melville, NY 11747

EXAMINER

SASAN, ARADHANA

ART UNIT	PAPER NUMBER
----------	--------------

1615

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

05/18/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@cdfslaw.com
tgiordano@cdfslaw.com

Office Action Summary	Application No. 14/294,660	Applicant(s) PERRETT ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/03/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-34,55 and 56 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☐ Claim(s) _____ is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☒ Claim(s) 1-34,55 and 56 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____ | 4) ☐ Other: _____ |

DETAILED ACTION

Notice of Pre-AIA or AIA status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Application

2. The claim amendments filed on 10/03/2014 are acknowledged.
3. Claims 35-54 were cancelled. New claims 55-56 were added. Claims 1-34 and 55-56 are pending.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28 and 55-56, drawn to a solid pharmaceutical composition and an orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid, classified in CPC A61K9/0056.
 - II. Claims 29-34, drawn to a method for treating an inflammatory condition of the gastrointestinal tract, classified in CPC A61K31/57.
5. The inventions are distinct, each from the other because of the following reasons:
6. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the

Art Unit: 1615

product as claimed can be practiced with another materially different product such as with a composition comprising leukotriene antagonists like montelukast.

7. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design and mode of operation. The inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

8. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classification or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

Art Unit: 1615

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

Art Unit: 1615

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARADHANA SASAN whose telephone number is (571)272-9022. The examiner can normally be reached on Mon thru Thurs: 6:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

Application/Control Number: 14/294,660

Page 7

Art Unit: 1615

Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aradhana Sasan/

Primary Examiner, Art Unit 1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Stephen PERRETT, et al.	Examiner:	Aradhana Sasan
Serial No.:	14/294,660	Group:	1615
Filed:	June 3, 2014	Dated:	October 3, 2014
For:	ORALLY ADMINISTERED CORTICOSTERIOD COMPOSITIONS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Filed Via EFS-Web
Confirmation No.: 3674

PRELIMINARY AMENDMENT

Prior to examination, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the Listing of Claims, which begins on page 2 of this paper; and

Remarks begin on page 7 of this paper.

The following Listing of Claims will replace all prior versions and Listings of Claims in the application.

Listing of Claims:

WHAT IS CLAIMED IS:

1. (Previously Presented) A solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.
2. (Previously Presented) The solid pharmaceutical composition of claim 1, wherein said solid pharmaceutical composition disintegrates within 30 seconds.
3. (Previously Presented) The solid pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.
4. (Previously Presented) The solid pharmaceutical composition of claim 1, further comprising an adhesive agent.
5. (Previously Presented) The solid pharmaceutical composition of claim 4, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums,

- alginic acid, modified alginic acids, and combinations thereof.
6. (Previously Presented) The solid pharmaceutical composition of claim 1, further comprising a disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.
 7. (Previously Presented) The solid pharmaceutical composition of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.
 8. (Previously Presented) The solid pharmaceutical composition of claim 1, which is substantially free of lubricant.
 9. (Previously Presented) The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.
 10. (Previously Presented) The solid pharmaceutical composition of claim 9, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.
 11. (Previously Presented) The solid pharmaceutical composition of claim 10, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.
 12. (Previously Presented) The solid pharmaceutical composition of claim 1, further comprising at least one antiviral agent.
 13. (Previously Presented) The solid pharmaceutical composition of claim 12, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and

- nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, puridine analogs, pyrimidine analogs, and uncategorized antiviral drugs.
14. (Previously Presented) The solid pharmaceutical composition of claim 12, wherein the antiviral agent selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclovir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.
 15. (Previously Presented) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).
 16. (Previously Presented) The pharmaceutical composition of claim 15, wherein the ODT comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol and/or saccharide.
 17. (Previously Presented) The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .
 18. (Previously Presented) The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 4 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .
 19. (Previously Presented) The pharmaceutical composition of claim 16, wherein the corticosteroid is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .

20. (Previously Presented) The pharmaceutical composition of claim 4, wherein the adhesive agent and the corticosteroid are intimately associated.
21. (Previously Presented) The pharmaceutical composition of claim 20, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.
22. (Previously Presented) The pharmaceutical composition of claim 20, wherein the corticosteroid is disposed on the surface of said adhesive agent.
23. (Previously Presented) The pharmaceutical composition of claim 16, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.
24. (Previously Presented) The pharmaceutical composition of claim 23, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.
25. (Previously Presented) The pharmaceutical composition of claim 23, wherein the ODT is in the form of a wafer or film.
26. (Previously Presented) The pharmaceutical composition of claim 16, wherein the ODT is in the form of a wafer or film.
27. (Previously Presented) An orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid selected from the group consisting of fluticasone, budesonide, mometasone, and salts, solvates and esters thereof, wherein the orally disintegrating tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.
28. (Previously Presented) The orally disintegrating tablet of claim 27, wherein the orally disintegrating tablet comprises about 0.05-0.3 mg fluticasone.
29. (Previously Presented) A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1.

30. (Previously Presented) The method of claim 29, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.
31. (Previously Presented) The method of claim 29, wherein said condition is eosinophilic esophagitis.
32. (Previously Presented) The method of claim 29, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.
33. (Previously Presented) The method of claim 29, wherein said condition is viral or bacterial pharyngitis.
34. (Previously Presented) The method of claim 29, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.
35. through 54. (Cancelled).
55. (New) The orally disintegrating tablet of claim 27, wherein the orally disintegrating tablet comprises about 0.01 to about 20 mg fluticasone.
56. (New) The solid pharmaceutical composition of claim 1 comprises about 0.01 to about 20 mg fluticasone.

REMARKS

By the present Amendment, claims 55 and 56 are added and claims 35-54 are cancelled. Applicants respectfully submit that the present Amendment introduces no new matter and that the claims pending in the application are fully supported by the specification and are patentable over the prior art. Allowance of this application is respectfully requested.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-2140. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-2140.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, or resolve any outstanding matters, the Examiner is sincerely invited to contact the Applicant's undersigned representative at the number indicated below.

Respectfully submitted,

/Sonsy P. RAJAN/ Reg. #68269

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Sonsy P. Rajan
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Attorney for Applicant

Electronic Acknowledgement Receipt

EFS ID:	20318887
Application Number:	14294660
International Application Number:	
Confirmation Number:	3674
Title of Invention:	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS
First Named Inventor/Applicant Name:	Stephen PERRETT
Customer Number:	100622
Filer:	Thomas Michael Rosselli/Julie Dascoli
Filer Authorized By:	Thomas Michael Rosselli
Attorney Docket Number:	EUR-119/02US
Receipt Date:	03-OCT-2014
Filing Date:	03-JUN-2014
Time Stamp:	07:53:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		pa.pdf	148059 4bd32a1bd4aebdfeaec894c65209ac1ebd3c3408	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Preliminary Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	7
Warnings:			
Information:			
Total Files Size (in bytes):		148059	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/294,660	Filing Date 06/03/2014	☒ To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO**APPLICATION AS FILED – PART I**

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	10/03/2014	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 36	Minus	** 54	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X \$420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/ANGELA JOHNSON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>		Attorney Docket No. EURA-119/02US	
		First Named Inventor Stephen PERRETT	
		Title ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS	
		Express Mail Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		
1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☐ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>35</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets _____] 6. Inventor's Oath or Declaration [Total Pages _____] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☐ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☒ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☒ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☒ Other: This application is a Continuation of U.S. Patent Application No. <u>12/896,005</u> . _____ _____ _____		
*Note: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 must be included in an Application Data Sheet (ADS). (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).			
19. CORRESPONDENCE ADDRESS			
☒ The address associated with Customer Number: <u>91543</u> OR ☐ Correspondence address below			
Name			
Address			
City	State	Zip Code	
Country	Telephone	Email	
Signature	/TRUPTI JOSHI/		Date
Name (Print/Type)	Trupti P. Joshi		Registration No. (Attorney/Agent)
		June 3, 2014	
		69,719	

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	EURA-119/02US
		Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Inventor Information:

Inventor 1					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Stephen		PERRETT		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Princeton	State/Province	NJ	Country of Residence i	US
Mailing Address of Inventor:					
Address 1	142 Leabrook Lane				
Address 2					
City	Princeton	State/Province	NJ		
Postal Code	08540	Country i	US		
Inventor 2					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Fredric	Jay	COHEN		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Washington Crossing	State/Province	PA	Country of Residence i	US
Mailing Address of Inventor:					
Address 1	52 Bailey Drive				
Address 2					
City	Washington Crossing	State/Province	PA		
Postal Code	18977	Country i	US		
Inventor 3					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Gopi		VENKATESH		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		EURA-119/02US	
		Application Number			
Title of Invention		ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS			
City	Vandalia	State/Province	OH	Country of Residence i	US
Mailing Address of Inventor:					
Address 1		780 Waldsmith Way			
Address 2					
City	Vandalia	State/Province	OH		
Postal Code	45377	Country i	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	91543		
Email Address	zpatdcdocketing@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		
Attorney Docket Number	EURA-119/02US	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	EUR-119/02US
		Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	91543		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	12896005	2010-10-01
Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12896005	Claims benefit of provisional	61247642	2009-10-01
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	EUR-119/02US
		Application Number	
Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	EURA-119/02US
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Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	EUR-119/02US
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Title of Invention	ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS		

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ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority to U.S. Provisional Application No. 61/247,642, filed October 1, 2009, the disclosure of which is herein incorporated by
5 reference in its entirety for all purposes.

TECHNICAL FIELD OF THE INVENTIONS

This invention relates to orally administered corticosteroid compositions, useful for the treatment of conditions associated with inflammation of the gastrointestinal tract.

10 BACKGROUND OF THE INVENTION

There are currently no approved topically administered anti-inflammatory medications for the treatment of conditions associated with inflammation of the upper portion of the gastrointestinal tract. One such condition, eosinophilic esophagitis (EE), is an inflammatory condition of the esophagus. It is characterized histologically
15 by a proliferation of eosinophils. The disease is painful, leads to difficulty swallowing and predisposes patients to food impaction and other complications.

Experimental and “off-label” treatments for EE include directing steroid medications formulated and approved for inhalation to the back of the throat such that they are not appreciably inhaled, and instructing the patient to rinse their mouth
20 immediately after administration and not to swallow food or water for two hours after administration. Rinsing is recommended because residual drug in the mouth and throat can lead to candidiasis infection, and swallowing is contraindicated because it may wash drug away from the esophagus. Aqueous corticosteroid preparations intended for oral inhalation through nebulization are also mixed with sugars to
25 produce a thickened and sweetened liquid for administration.

Off-label treatments for EE also include administration of corticosteroid tablets containing steroids such as prednisolone. However, systemic administration of corticosteroids is associated with a number of known and undesirable side-effects. For example, oral prednisolone can produce generalized suppression of immune

function, and in children, particularly troubling side-effects from long term systemic exposure include growth retardation, which may lead to a reduction in adult height.

There is therefore a need in the art for orally administered corticosteroid formulations which provide topical (rather than systemic) treatment of inflammation of the gastrointestinal tract, particularly inflammation of the upper gastrointestinal tract, such as EE.

SUMMARY OF THE INVENTION

In one embodiment, the present invention is directed to a solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralcorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test, and/or which disintegrates within 60 seconds when placed in the oral cavity of a human.

In another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, and a pharmaceutically acceptable substantially non-aqueous liquid.

In another embodiment, the present invention is directed to a method for treating an inflammatory condition of the gastrointestinal tract. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

In yet another embodiment, the present invention is directed to a liquid pharmaceutical composition comprising a corticosteroid, a pharmaceutically acceptable aqueous or substantially non-aqueous liquid, and a pharmaceutically acceptable phase change agent dissolved or suspended in the liquid, wherein after administration to a patient, the composition undergoes a change in physical properties upon contact with the gastrointestinal tract of the patient.

In yet another embodiment, the present invention is directed to a composition in solid or liquid form additionally comprising cyclodextrins.

The compositions of the present invention are useful for various conditions including the treatment of inflammatory conditions of the gastrointestinal tract.

Accordingly, the present invention also provides a method for treating inflammatory conditions of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

5

DETAILED DESCRIPTION OF THE INVENTION

All documents (e.g., patents, patent publication, journal articles, etc.) cited in the present application are incorporated by reference in their entirety for all purposes.

The term "drug", "active" or "active pharmaceutical ingredient" as used herein
10 includes a pharmaceutically acceptable and therapeutically effective compound (e.g., corticosteroid), pharmaceutically acceptable salts, stereoisomers and mixtures of stereoisomers, solvates (including hydrates), and/or esters thereof (e.g., of corticosteroid).

The terms "orally disintegrating tablet", "orally dispersing tablet", or "ODT"
15 refer to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing. The rate of oral disintegration can vary, but is significantly faster than the rate of oral disintegration of conventional solid dosage forms or chewable solid dosage forms (i.e., tablets or capsules) which are intended to be swallowed immediately after administration. ODT
20 compositions of the present invention can contain pharmaceutically acceptable ingredients which swell, dissolve or otherwise facilitate the disintegration or dissolution of the ODT composition. Such ingredients can include pharmaceutical a disintegrant, a sugar alcohol, a saccharide, or a mixture thereof, a water-soluble binder, a meltable solid (e.g., a wax), which can release the corticosteroid upon
25 entering the stomach, etc.

The term "about", as used herein to refer to a numerical quantity, includes "exactly". For example, "about 60 seconds" includes 60 seconds, exactly, as well as values close to 60 seconds (e.g., 50 seconds, 55 seconds, 59 seconds, 61 seconds, 65 seconds, 70 seconds, etc.). When the term "about" is used in reference to a range of
30 values, the term "about" refers to both the minimum and maximum value of the range (e.g., "about 1-50 μm " means "about 1 μm to about 50 μm ").

The term “adhesive agent”, as used herein refers to agents which promote adhesion of the corticosteroid to biological surfaces, and includes, but is not limited to bio-adhesive agents. Adhesive agents can include compounds which adhere to the oropharyngeal mucosa, as well as compounds which increase the residence time of
5 the compositions of the present invention on the oropharyngeal mucosa of a patient.

The term “intimately associated”, as used herein to describe the spatial relationship between two or more components of a composition refers to components that are intimately mixed, such as for example in mixtures, coatings and matrices.

The term “having no significant systemic glucocorticoid or mineralocorticoid activity”, as used herein refers to corticosteroid compositions which do not provide a
10 generalized effect in the body through absorption into the circulation, but do provide local effects through topical contact with a diseased tissue. Corticosteroids which have high systemic glucocorticoid potencies when administered orally include e.g., hydrocortisone, prednisone, prednisolone, methylprednisolone, dexamethasone,
15 betamethasone, etc.) or mineralocorticoid potencies (e.g., aldosterone). These corticosteroids may be suitable for use in the compositions of the present invention if they are used at a sufficiently low dose, or are otherwise formulated such that they do not have significant systemic glucocorticoid or mineralocorticoid activity. Exemplary corticosteroids suitable for use in the compositions of the present invention include,
20 but are not limited to budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone and triamcinolone.

The term “bio-gelling polymer” as used herein refers to a polymer forms a gel under GI tract physiological conditions, for example, upon contact with physiological fluids or at physiological temperature.

25 The term "substantially non-aqueous liquid" refers to liquids which are completely anhydrous, or include only small amounts of water (e.g. less than about 10% water, for example less than about 9%, less than about 8%, less than about 7%, less than about 6%, less than about 5%, less than about 4%, less than about 3%, less than about 2%, or less than about 1% water).

30 The term "phase change agent" refers to an agent which, upon dissolution or suspension in the substantially non-aqueous liquids of the present invention, causes the liquid pharmaceutical compositions of the present invention to undergo a change

in physical properties after administration to a patient. For example such changes in physical properties include precipitation of the dissolved or suspended components of the composition (e.g. the corticosteroid, optional excipients, and the phase change agent); gelation of the composition (e.g., formation of a hydrogel of the phase change agent and optionally excipients, wherein the hydrogel comprises at least a portion of the corticosteroid); or an increase in viscosity of the composition. These changes in physical properties have the effect of increasing or enhancing contact of the corticosteroid to the mucosa of the gastrointestinal tract of the patient.

Unless indicated otherwise, all percentages and ratios are calculated by weight. Unless indicated otherwise, all percentages and ratios are calculated based on the total composition.

The solid and liquid pharmaceutical compositions of the present invention are suitable for topical administration of a corticosteroid to the gastrointestinal tract, for example the upper gastrointestinal tract such as the esophagus. Topical administration of a corticosteroid for conditions associated with inflammation of the gastrointestinal tract is desirable because it results in fewer side-effects than systemic corticosteroid administration. Such side-effects are reduced still further with the use of corticosteroids which do not have significant systemic glucocorticoid or mineralocorticoid activity because of their reduced systemic exposure.

The pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the gastrointestinal tract, for example inflammatory conditions of the upper gastrointestinal tract such as the esophagus. Thus, the present invention includes treating inflammatory conditions of the gastrointestinal tract by administering to a patient in need thereof a solid or liquid pharmaceutical composition of the present invention. Inflammatory conditions of the gastrointestinal tract which may be treated according to the present invention include inflammation of the esophagus, inflammation of the glottis, inflammation of the epiglottis, inflammation of the tonsils, inflammation of the oropharynx, eosinophilic esophagitis, gastroesophageal reflux disease (GERD), non-erosive reflux disease (NERD), erosive esophagitis, Barrett's esophagus, eosinophilic gastroenteritis, hypereosinophilic syndrome, corrosive (caustic) chemical esophagitis, radiation-induced esophagitis, chemotherapy-induced esophagitis, transient drug-induced esophagitis (also known as medication esophagitis), persistent drug-induced

esophagitis, Crohn's disease of the esophagus, scleroderma, and scleroderma sine scleroderma, systemic lupus erythematosus, systemic vasculitides, leukocytoclastic vasculitis, polyarteritis nodosa, Churg-Strauss syndrome, rheumatoid vasculitis, and pseudomembranous esophagitis.

5 In other embodiments, the pharmaceutical compositions of the present invention are suitable for treating inflammatory conditions of the gastrointestinal tract such as an autoimmune disease, Behcet's syndrome, Kawasaki disease, X-linked lymphoproliferative syndrome; an infectious viral disease caused by one or more of the following viruses: Adenoviridae, Coronaviridae, Coxsackie virus, Herpes simplex, 10 HIV, Influenza (Type A), Lassa virus, Epstein-Barr virus, Parainfluenza, or Respiratory syncytial virus; an infectious bacterial disease caused by one or more of the following bacteria: Arcanobacterium hemolyticum, Chlamydia (Chlamydomphila), Corynebacterium, Francisella tularensis, Group A, C, G Streptococcus, S. pneumoniae, S. pyogenes, Haemophilus influenza type B, Mycoplasma pneumonia, 15 Neisseria gonorrhea, Multiple (e.g. peritonsillar cellulitis/abscess); an infectious fungal disease caused by Candida (e.g. Candida albicans) or Histoplasma (e.g. H capsulatum); inflammation caused by injury or an irritant selected from the group consisting of an airway foreign body, chloroacetophenone, chlorobenzylidene malononitrile, chronic smoke exposure, morpholine, sulfuryl fluoride, and scalded 20 throat; lepidopterism, Seasonal allergic pharyngitis, and Stevens-Johnson syndrome; or periodic fever; etc.

 In one embodiment, the present invention includes a method for treating inflammation of the esophagus comprising administering to a patient in need thereof a pharmaceutical composition of the present invention. In one such embodiment, the 25 present invention includes a method for treating eosinophilic esophagitis comprising administering to a patient in need thereof a pharmaceutical composition of the present invention.

 In another embodiment, the present invention includes a method for treating gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or 30 erosive esophagitis comprising administering to an individual in need thereof a pharmaceutical composition of the present invention.

In another embodiment, the present invention includes a method for treating a food allergy with an identified allergen, e.g., “atopic IBS”, and “atopic bowel”.

In one embodiment, the present invention provides a solid pharmaceutical composition which comprises less than or equal to 20 mg of a corticosteroid, wherein
5 the composition has no significant systemic glucocorticoid or mineralocorticoid activity, and wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test. In another embodiment, the solid pharmaceutical compositions of the present invention disintegrate within 60 seconds in the oral cavity of the patient, e.g. human. In still
10 other embodiments, the solid pharmaceutical compositions of the present invention disintegrate within 30 seconds in simulated saliva (using the USP <701> Disintegration Test), or in the oral cavity of a patient. In still other embodiments, the solid or liquid pharmaceutical compositions of the present invention topically provide a therapeutically effective amount of a corticosteroid to inflamed tissues of the
15 gastrointestinal tract, after oral administration to a patient in need thereof.

Solid pharmaceutical compositions of the present invention can include, for example, an ODT (as described herein), a wafer, a film, or other solid dosage form which disintegrates or dissolves rapidly in the mouth to form a solution or dispersion of a corticosteroid, which can readily be swallowed.

20 In another embodiment, the present invention provides a liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable solvent, wherein the liquid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity. In one such embodiment the composition also includes a pharmaceutically acceptable bio-gelling polymer
25 dissolved in the solvent, and the composition increases in viscosity upon contact with the gastrointestinal tract of an individual. In other embodiments, the liquid compositions of the present invention comprise a corticosteroid complex with a cyclodextrin, typically suspended or dissolved in a liquid carrier. The liquid compositions of the present invention may be in the form of a solution or a
30 suspension. Liquid pharmaceutical compositions according to the present invention are compositions which are liquids at standard temperature and pressure conditions.

Suitable pharmaceutically acceptable liquids which may be used in the liquid pharmaceutical compositions of the present invention include, for example, alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, N-methyl-2-pyrrolidone (NMP), 2-pyrrolidone, glycerol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, ethyl butyrate, dibutyl malonate, tributyl citrate, tri-n-hexyl acetylcitrate, diethyl succinate, diethyl glutarate, diethyl malonate, triethyl citrate, triacetin, tributyrin, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, caprolactam, N,N-diethyl-m-toluamide, 1-dodecylazacycloheptan-2-one, 1,3-dimethyl-3,4,5,6-tetrahydro-2(1H)-pyrimidinone, and combinations thereof. In one embodiment, the liquid is selected from the group of alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, glycerol and combinations thereof. In one such embodiment, the liquid is selected from the group of ethanol, glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof. In other embodiments, the liquid pharmaceutical compositions of the present invention can comprise aqueous suspensions or solutions of a corticosteroid.

In one embodiment the bio-gelling polymer is a thermosensitive polymer. Suitable thermosensitive polymers include polyacrylamides, such as poly(N-isopropylacrylamide), as well as poly(ether-ester) copolymers, such as poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol). Such thermosensitive polymers can precipitate or cause an increase in viscosity of the liquid compositions of the present invention upon administration to a patient, and subsequent warming in the gastrointestinal tract. Thus, the compositions of the invention precipitate on or have a longer residence time on the gastrointestinal mucosa the patient, thereby increasing the topical contact of the corticosteroid on the gastrointestinal mucosa. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

In another embodiment, the compositions of the present invention include a bioadhesive agent, which is a lipid or a mixture of lipids. Such lipids or lipid mixtures may undergo a phase transition on contact with wetted biological surfaces to form an adhesive film. Examples of such lipids include mixtures of so-called membrane and non-membrane lipids which will typically form lamellar and non-

lamellar structures, such as hexagonal or cubic phases, respectively. Examples of such lipids are glycerphospholipids such as phosphatidyl choline, and diacyl glycerols such as glycerol dioleate. Such self-organizing structures demonstrate superior spreading and adhesion to biological surfaces and have the advantage of being pharmaceutically acceptable materials. Advantageously the active agent, e.g. a corticosteroid may be dissolved in the lipid component.

Suitable non-aqueous solvents which may be included in the liquid pharmaceutical compositions of the present invention include pharmaceutically acceptable non-aqueous solvents in which the particular bio-gelling polymer is soluble. For example, the solvent may be an alcohol (e.g., ethanol), N-methylpyrrolidone (NMP), glycerol, propylene glycol, liquid polyethylene glycol, diethylene glycol monoethyl ether and mixtures thereof. In certain embodiments the solvent is water-miscible and the bio-gelling polymer is water-insoluble, so that upon administration the solvent mixes rapidly with the water from the digestive tract of the patient, causing the bio-gelling polymer and corticosteroid to precipitate on the gastrointestinal mucosa of the patient. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

Other bio-gelling polymers which may be included within the liquid pharmaceutical compositions of the present invention include cellulose derivatives (e.g., esters and/or ethers, crosslinked cellulose esters and/or ethers) cellulose esters, methacrylic acid and methacrylate polymers, polylactides, polyglycolides, polycaprolactones, polydioxanones, polycarbonates, polyhydroxybutyrates, polyalkylene oxalates, polyanhydrides, polyamides, polyesteramides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene succinates, poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, and copolymers, terpolymers and mixtures thereof. Bio-gelling polymers swell, and/or form hydrogels upon contact with moisture in the gastrointestinal tract, thereby adhering or increasing the viscosity of the compositions of the present invention on the mucosa of the gastrointestinal tract. Consequently, the contact of the corticosteroid with the gastrointestinal mucosa is enhanced and/or prolonged.

In certain embodiments, the liquid pharmaceutical compositions of the present invention increase in viscosity upon contact with the gastrointestinal tract of an

individual. In one embodiment, the increase in viscosity is at least 50% (relative to the viscosity prior to administration). In another such embodiment, the increase in viscosity is at least 100%. In yet another such embodiment, the increase in viscosity is at least 200%. The viscosity of the compositions before contact with the
5 gastrointestinal tract of an individual may be measured using a viscometer. The change in viscosity of the compositions upon contact with the gastrointestinal tract of an individual may be determined by measuring the viscosity of the composition under simulated physiological conditions. For example, the viscosity of a given composition may be measured in simulated saliva.

10 Suitable corticosteroids which may be included in the pharmaceutical compositions of the present invention include budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, tixocortol and salts, solvates, and esters thereof. In a particular embodiment, the compositions of the present invention comprise fluticasone. In other embodiments, the compositions of the present
15 invention comprise budesonide. Corticosteroids which typically have systemic glucocorticoid or mineralocorticoid activity when administered orally can also be used in the compositions of the present invention, if the composition is modified to reduce or suppress systemic uptake of the corticosteroid.

The amount of corticosteroid present in the pharmaceutical compositions of
20 the present invention will depend upon the particular corticosteroid utilized. In general, however, the amount will be selected so as to maximize the therapeutic benefit from topical administration while minimizing systemic absorption. In the case of solid pharmaceutical compositions of the present invention, the amount of corticosteroid in the composition typically is less than or equal to 20 mg. In one
25 embodiment the amount of corticosteroid in the pharmaceutical composition is between about 0.01 mg and about 20 mg. In another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 1 mg and about 15 mg. In still another embodiment the amount of corticosteroid in the pharmaceutical composition is between about 2 mg and about 10 mg. In yet another embodiment the
30 amount of corticosteroid in the pharmaceutical composition is between about 2 mg and about 5 mg. In still other embodiments, the amount of corticosteroid is about 0.01 mg, about 0.02 mg, about 0.03 mg, about 0.04 mg, about 0.05 mg, about 0.06 mg, about 0.07 mg, about 0.08 mg, about 0.09 mg, about 0.1 mg, about 0.2 mg, about

0.3 mg, about 0.4 mg, about 0.5 mg, about 1 mg, about 2 mg, about 3 mg, about 4 mg, about 5 mg, about 6 mg, about 7 mg, about 8 mg, about 9 mg, about 10 mg, about 11 mg, about 12 mg, about 13 mg, about 14 mg, about 15 mg, about 16 mg, about 17 mg, about 18 mg, about 90 mg, or about 20 mg, inclusive of all ranges and subranges
5 therebetween.

Typical amounts of corticosteroid in the solid pharmaceutical compositions of the present invention include about 0.25 mg, about 0.5 mg, about 1 mg, about 1.5 mg, about 2 mg, about 2.5 mg, about 3 mg, about 3.5 mg, about 4 mg, about 4.5 mg and about 5 mg. In the case of liquid pharmaceutical compositions of the present
10 invention, the concentration of corticosteroid in the composition typically is such that an amount of corticosteroid consistent with the amounts described above (i.e., 0.01 mg to 20 mg) may be conveniently administered to an individual. For example, the concentration of corticosteroid may be such that a single pump from a spray pump device delivers about 0.05 mg, or any other therapeutically effective pre-selected
15 amount, of corticosteroid to the oral cavity of an individual. In a particular embodiment, the compositions of the present invention comprise about 0.25 mg of fluticasone.

Upon administration of a solid pharmaceutical composition of the present invention to an individual, the composition disintegrates in the patient's oral cavity.
20 In one embodiment, the composition of the present invention is in the form of an ODT. An ODT comprises drug containing particles (e.g., a corticosteroid as described herein optionally coated or combined with an adhesive agent as described herein), combined with rapidly dispersing microgranules. Rapidly dispersing microgranules can be prepared as described in US 2005/0232988 or US 20010014340
25 by granulating a disintegrant having an average particle size of not more than about 30 μm with a sugar alcohol and/or saccharide having an average particle size of not more than about 30 μm . The granulation can be carried out, for example, in a high shear granulator with approximately 20-25% water as the granulating fluid, and if needed wet milled and dried to produce rapidly dispersing microgranules having an
30 average particle size of not more than about 300 μm (e.g., about 175-300 μm).

The ratio of the disintegrant to the sugar alcohol, saccharide, or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01, for example about 90/10, about 91/9, about 92/8, about 93/7, about 94/6, about

95/5, about 96/4, about 97/3, about 98/2, about 99/1, inclusive of all values, ranges, and subranges therebetween.

The ratio of the rapidly dispersing microgranules to drug-containing particles ranges from about 5/1 to about 1/1, including about 5/1, 4/1, 3/1, 2/1, 1/1, inclusive of
5 all values, ranges, and subranges therebetween.

The corticosteroid containing particles of the ODT dosage form should also have a small enough particle size such that after disintegration of the ODT in the oral cavity of the patient, a smooth, easy-to-swallow suspension results. In most embodiments in which the pharmaceutical compositions of the present invention is
10 provided as an ODT dosage form, the average particle size of the taste-masked non-opioid analgesic/opioid analgesic drug-containing microparticles is not more than about 400 μm , or in some embodiments not more than about 300 μm .

The ODT dosage form as described herein may also include pharmaceutically acceptable excipients typically used in disintegrating tablet formulations such as
15 microcrystalline cellulose and spray dried mannitol (compressible diluents), croscarmellose sodium or crospovidone (super disintegrant), coloring agents, and optionally magnesium stearate or sodium stearyl fumarate (lubricant intragranularly mixed or used externally to lubricate die and punch surfaces).

Tablet dosage forms, including ODT dosage forms, comprising the
20 pharmaceutical composition of the present invention have a low friability, e.g., less than about 1%, (e.g., less than about 0.9%, less than about 0.8%, less than about 0.7%, less than about 0.6%, less than about 0.5%, less than about 0.4%, less than about 0.3%, etc., inclusive of all ranges and subranges therebetween) in order to have sufficient durability to withstand handling, shipping, and/or packaging in push-
25 through blister packaging.

A non-limiting list of suitable disintegrants for the rapidly dispersing microgranules includes crospovidone (cross-linked PVP), sodium starch glycolate, cross-linked sodium carboxymethylcellulose, calcium silicate, and low substituted hydroxypropyl cellulose. The amount of disintegrant in the ODT is typically in the
30 range of about 1% to about 10% by weight.

A non-limiting list of suitable sugar alcohols includes mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol and

combinations thereof. A non-limiting list of suitable saccharides includes lactose, sucrose, maltose, and combinations thereof. The amount of sugar alcohol and/or saccharide in the ODT ranges from about 30% to about 70% by weight.

Pharmaceutically acceptable excipients include fillers, diluents, glidants, disintegrants, binders and lubricants. Other pharmaceutically acceptable excipients include acidifying agents, alkalizing agents, preservatives, antioxidants, buffering agents, chelating agents, coloring agents, complexing agents, emulsifying and/or solubilizing agents, flavors, perfumes, humectants, sweetening agents and wetting agents.

Examples of suitable fillers, diluents and/or binders include lactose (e.g. spray-dried lactose, α -lactose, β -lactose, Tabletose[®], various grades of Pharmatose[®], Microtose[®] or Fast-Flo[®]), microcrystalline cellulose (various grades of Avicel[®], Ceolus[®], Elcema[®], Vivacel[®], Ming Tai[®] or Solka-Floc[®]), hydroxypropylcellulose, L-hydroxypropylcellulose (low substituted), low molecular weight hydroxypropyl methylcellulose (HPMC) (e.g. Methocel E, F and K from Dow Chemical, Metolose SH from Shin-Etsu, Ltd), hydroxyethylcellulose, sodium carboxymethylcellulose, carboxymethylhydroxyethylcellulose and other cellulose derivatives, sucrose, agarose, sorbitol, mannitol, dextrans, maltodextrins, starches or modified starches (including potato starch, maize starch and rice starch), calcium phosphate (e.g. basic calcium phosphate, calcium hydrogen phosphate, dicalcium phosphate hydrate), calcium sulfate, calcium carbonate, sodium alginate and collagen.

Examples of suitable diluents include e.g. calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, microcrystalline cellulose, powdered cellulose, dextrans, dextrin, dextrose, fructose, kaolin, lactose, mannitol, sorbitol, starch, pregelatinized starch, sucrose and sugar.

Examples of suitable disintegrants include e.g. alginic acid or alginates, microcrystalline cellulose, hydroxypropyl cellulose and other cellulose derivatives, croscarmellose sodium, crospovidone, polacrillin potassium, sodium starch glycolate, starch, pregelatinized starch, and carboxymethyl starch (e.g. Primogel[®] and Explotab[®]).

Specific examples of glidants and lubricants include stearic acid, magnesium stearate, calcium stearate or other metallic stearates, talc, waxes and glycerides, light

mineral oil, PEG, glyceryl behenate, colloidal silica, hydrogenated vegetable oils, corn starch, sodium stearyl fumarate, polyethylene glycols, alkyl sulfates, sodium benzoate and sodium acetate.

Other excipients include e.g. flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents, absorption enhancing agents and agents for modified release.

Other functional excipients such as cyclodextrins may be used, for example as taste-masking agents (e.g., by means of their complexation with the corticosteroid). Cyclodextrins may also be used as a carrier and/or a dispersant to facilitate delivery and distribution of the corticosteroid at the intended site of therapeutic activity.

Compositions of the present invention in the form of an ODT disintegrate into corticosteroid containing particles while sugar alcohol/saccharide-containing granules included within the composition rapidly dissolve, thereby forming a smooth suspension that can be readily swallowed.

Other corticosteroid-containing orally disintegrating or orally dissolving dosage forms such as wafers or films can also be used. For example, wafers can include dried or lyophilized compositions such as orally disintegrating or dissolving dosage forms prepared using Zydis[®] lyophilization technology (e.g., as described in U.S. Patent No. 6,316,027), containing a corticosteroid as the active pharmaceutical ingredient. Film dosage forms can include edible films such as those described in US 6,596,298 or US 6,740,332, containing a corticosteroid as the active pharmaceutical ingredient.

The rate of disintegration of the compositions of the present invention in the oral cavity of an individual can be on the order of about 60 seconds or less, about 50 seconds or less, about 40 seconds or less, about 30 seconds or less, about 20 seconds or less, or about 10 seconds or less.

The rate of disintegration of the solid pharmaceutical compositions of the present invention can be measured using various in vitro test methods, for example the USP <701> Disintegration Test. When using the USP <701> Disintegration Test, the rate of disintegration of the compositions of the present invention typically is

about 60 seconds or less, about 45 seconds or less, about 30 seconds or less, about 20 seconds or less, or about 10 seconds or less.

In other embodiments, the solid pharmaceutical compositions of the present invention can have any rate of disintegration or dissolution in the oral cavity of a patient which provides a therapeutically effective amount of corticosteroid to the inflamed tissues of the gastrointestinal tract. For example, in some embodiments, solid pharmaceutical compositions according to the present invention include compositions that provide about 0.5 mg to about 20 mg of the corticosteroid to the inflamed tissues of the gastrointestinal tract after oral administration.

In one embodiment, the solid pharmaceutical compositions of the present invention include an adhesive agent. Suitable adhesive agents include sucrose aluminum sulfate complex, chitosan and derivatives thereof (e.g., trimethylchitosan, chitosan salts), polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, Eudragit[®] polymers (E, L, S, NE, RL, and RS grades), carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

In certain embodiments of the solid pharmaceutical compositions of the present invention, the corticosteroid and the adhesive agent are intimately associated. In one such embodiment the solid pharmaceutical composition comprises corticosteroid surrounded or encapsulated by the adhesive agent. In another such embodiment the solid pharmaceutical composition comprises corticosteroid disposed on the surface of the adhesive agent. In still other embodiments, the solid pharmaceutical composition comprises corticosteroid mixed or granulated with the adhesive agent.

Topical administration of a corticosteroid to the oral cavity of individuals has been associated with candidiasis infection. Consequently, in one embodiment

pharmaceutical compositions of the present invention include an antifungal agent. Suitable antifungal agents include, but are not limited to mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and other "uncategorized" antifungals recognized in the art that do not fall within any of the above categories (e.g., tolnaflate and ciclopirox). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abafungin, amorolfine, anidulafungin, bifonazole, butenafine, butoconazole, candicin, caspofungin, ciclopirox, clotrimazole, econazole, fenticonazole, filipin, fluconazole, flucytosine, griseofulvin, isavuconazole, isoconazole, itraconazole, ketoconazole, micafungin, miconazole, miconazole nitrate, naftifine, natamycin, nystatin, oxiconazole, posaconazole, pramiconazole, ravuconazole, rimocidin, setaconazole, sulconazole, terbafine, terconazole, tioconazole, tolnaftate, undecylenic acid, and voriconazole.

In another embodiment, pharmaceutical compositions of the present invention include an antiviral agent. Antiviral agents which may be included in the solid pharmaceutical compositions of the present invention include interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, guanosine analogs, puridine analogs, pyrimidine analogs, and other "uncategorized" antiviral drugs recognized in the art which do not fall within any of the above classes (e.g. foscarnet and miltefosine). For example, suitable antifungal agents which may be included in the solid pharmaceutical compositions of the present invention include abacavir, aciclovir (also known as acyclovir), adefovir, amantadine, amdoxovir, amprenavir, aplaviroc, apricitabine, arbidol, atazanavir, bevirimat, BMS-488043, boceprevir, brivudine, cidofovir, DCM205, docosanol, delavirdine, didanosine, duronavir, efavirenz, elvitegravir, elvucitabine, emtricitabine, enfuvirtide, epigallocatechin gallate, etravirine, famciclovir, fosamprenavir, ganciclovir, globoidnan A, griffithsin, ibalizumab, idoxuridine, indinavir, lamivudine, lopinavir, lovirodine, maraviroc, nelfinavir, nevirapine, oseltamivir, pegylated interferon α -2a, pegylated interferon α -2b, penciclovir, peramivir, plerixafor, PRO 140, racivir, raltegravir, ritonavir, ribavirin, rimantadine, rilpivirine, saquinavir, stampidine,

stavudine, tenofovir, tipranavir, TNX-355, trifluridine, tromantadine, valaciclovir, valganciclovir, vicriviroc, vidarabione, viramidine, vivecon, zalcitabine, zanamivir, and zidovudine.

In one embodiment, the solid pharmaceutical compositions of the present invention comprise corticosteroid-containing granules. The corticosteroid-containing granules may be granules comprising corticosteroid crystals and a film-forming binder, e.g., prepared by granulation. The corticosteroid crystals can have an average particle size ranging from about 1-300 μm , for example about 1-50 μm , about 1-100 μm , about 1-150 μm , about 1-200 μm , about 1-250 μm , about 50-100 μm , about 50-150 μm , about 50-200 μm , about 50-250 μm , about 50-300 μm , about 100-150 μm , about 100-200 μm , about 150-200 μm , about 150-250 μm , about 150-300 μm , about 200-250 μm , about 200-300 μm , or about 250-300 μm .

In another embodiment, the corticosteroid may be in the form of crystals. Such crystals may have an average size in the sub-micron range (e.g., average particle size of about $< 1 \mu\text{m}$), or may be nanoparticles (e.g., average particle size in the range of about 1-100 nm).

In yet another embodiment, the corticosteroid may be present in amorphous form, for example in association with a stabilizing agent which limits drug recrystallization, e.g., polyvinylpyrrolidone (PVP) (including homo- and copolymers of polyvinylpyrrolidone and homopolymers or copolymers of N-vinylpyrrolidone); crospovidone; gums; cellulose derivatives (including hydroxypropyl methylcellulose (HPMC), hydroxypropyl methylcellulose phthalate, hydroxypropyl cellulose, ethyl cellulose, hydroxyethylcellulose, sodium carboxymethyl cellulose, calcium carboxymethyl cellulose, sodium carboxymethyl cellulose, and others); dextran; acacia; homo- and copolymers of vinyl lactam, and mixtures thereof, cyclodextrins; gelatins; hypromellose phthalate; sugars; polyhydric alcohols; polyethylene glycol (PEG); polyethylene oxides; polyoxyethylene derivatives; polyvinyl alcohol; propylene glycol derivatives and the like, sodium lauryl sulphate, Tween[®] surfactants, Eudragit[®] polymers; and combinations thereof.

The film-forming binder may comprise any suitable binder used in granulation. Non-limiting examples of suitable film-forming binders include water-soluble, alcohol-soluble or acetone/water soluble binders, e.g. polyvinylpyrrolidone

(PVP), corn starch, polyethylene oxide, polyethylene glycol, hydroxypropyl methylcellulose (HPMC), methylcellulose, or hydroxypropylcellulose (HPC). The amount of film-forming binder in the corticosteroid-containing granules can range from about 0.5% to about 10%, including about 0.5%-1%, about 0.5%-2%, about 5 0.5%-5%, about 0.5%-7%, about 1%-2%, about 1%-5%, about 1%-7%, about 1%-10%, about 2%-5%, about 2%-7%, about 2%-10%, about 5%-7%, about 5%-10%, and about 7%-10%.

The corticosteroid-containing granules of the present invention may also include other pharmaceutically acceptable ingredients, for example, fillers or diluents. 10 Non-limiting examples of other pharmaceutically acceptable ingredients for the corticosteroid-containing granules include, for example, mannitol, lactose, microcrystalline cellulose, potassium sulfate, calcium phosphate, modified starch, and mixtures thereof. The amount of other pharmaceutically acceptable ingredients (e.g. fillers or diluents) in the corticosteroid-containing granules can range from about 5%- 15 80%, including about 5%-70%, about 5%-60%, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, about 5%-15%, about 5%-10%, about 10%-70%, about 10%-60%, about 10%-50%, about 10%-40%, about 10%-30%, about 10%-20%, about 10%-15%, about 20%-70%, about 20%-60%, about 20%-50%, about 20%-40%, about 20%-30%, about 20%-25%, about 30%-70%, about 30%-60%, about 30%-50%, about 20 30%-40%, about 30%-35%, about 40%-70%, about 40%-60%, about 40%-50%, about 40%-45%, about 50%-70%, about 50%-60%, about 50%-55%, about 60%-70%, or about 60%-65%.

In another embodiment, the corticosteroid-containing granules of the present invention can be in the form of corticosteroid-layered beads. Corticosteroid-layered 25 beads comprise a core, e.g. a pharmaceutically acceptable sugar bead, coated with a corticosteroid layer. Such corticosteroid-layered beads can be prepared, for example, by dissolving or suspending corticosteroid in a polymeric binder solution, which is then sprayed or coated onto inert particles (e.g., sugar spheres or cellulose spheres (Cephadrin®)). Suitable polymeric binders include any of those disclosed herein, for 30 example starches, modified celluloses (e.g., hydroxypropylcellulose, carboxymethylcellulose sodium), alginic acid, polyvinyl pyrrolidone (povidone), and mixtures thereof. The amount of corticosteroid in the corticosteroid layer, and the thickness of the corticosteroid layer can be modified to provide a therapeutically

effective dose of corticosteroid. The corticosteroid-containing layer comprises about 90%-99% corticosteroid, and about 1% to about 10% binder.

The corticosteroid-containing granules of the present invention can be prepared by any suitable method. For example, the corticosteroid-containing granules
5 can be prepared by granulation of corticosteroid crystals, one or more disintegrants, and one or more fillers (e.g., sugar alcohol, saccharide and/or microcrystalline cellulose) in a high shear granulator or a fluid-bed granulator using a solution of one or more polymeric binders, and dried in fluid bed equipment or on trays in a conventional oven to produce the corticosteroid-containing granules.

10 The solid pharmaceutical compositions of the present invention may include rapidly dispersing granules comprising a disintegrant and a sugar alcohol and/or a saccharide. The disintegrant-containing granules can include disintegrants or so-called super-disintegrants, e.g. crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethyl cellulose, low substituted hydroxypropylcellulose,
15 and mixtures thereof. The amount of disintegrant in the rapidly dispersing granules can range from about 1%-10%, or about 5%-10% of the total weight of the rapidly dispersing granules, including all ranges and subranges therebetween.

Sugar alcohols are hydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl
20 group. Non-limiting examples of suitable sugar alcohols for the rapidly dispersing granules of the pharmaceutical compositions of the present invention include e.g. arabitol, isomalt, erythritol, glycerol, lactitol, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof. The term "saccharide" is synonymous with the term "sugars" includes monosaccharides such as glucose, fructose, the lactose, and ribose; and
25 disaccharides such as sucrose, lactose, maltose, trehalose, and cellobiose. In one embodiment, non-limiting examples of suitable saccharides for use in the compositions of the present invention include e.g. lactose, sucrose, maltose, and mixtures thereof. In another embodiment, the rapidly dispersing granules comprise at least one disintegrant in combination with a sugar alcohol. In another embodiment,
30 the rapidly dispersing granules comprise at least one disintegrant in combination with a saccharide. In yet another embodiment, the disintegrant-containing granules comprise at least one disintegrant in combination with a sugar alcohol and a saccharide. The amount of sugar alcohol and/or saccharide in the rapidly dispersing

granules ranges from about 99%-90%, or about 95%-90% of the total weight of the disintegrant-containing granules, including all ranges and subranges therebetween. In one embodiment, the average particle size of a sugar alcohol and/or saccharide is 30 μm or less, for example about 1-30 μm , about 5-30 μm , about 5-25 μm , about 5-20 μm , about 5-15 μm , about 5-10 μm , about 10-30 μm , about 10-25 μm , about 10-20 μm , about 10-15 μm , about 15-30 μm , about 15-25 μm , about 15-20 μm , about 20-30 μm , about 20-25 μm , or about 25-30 μm .

The corticosteroid-containing particles (e.g., crystals, granules, or drug-layered beads) of the solid pharmaceutical compositions of the present invention can also be coated with a taste-masking layer to improve the palatability of the composition. The corticosteroid-containing particles can be taste-masked by coating the corticosteroid-containing particles (e.g., crystals, granules, or drug-layered beads) with a water-insoluble polymer. Non-limiting examples of suitable water-insoluble polymers for the taste-masking layer include ethylcellulose, polyvinyl acetate (PVA), cellulose acetate (CA), cellulose acetate butyrate (CAB), methacrylate copolymers, such as those available under the tradename "EUDRAGIT" (e.g., type RL, RS, and NE30D), and combinations thereof.

In one embodiment, the water-insoluble polymer is ethylcellulose having a viscosity of about 90-110 cps when tested in an Ubbelohde viscometer as a 5 weight % 80:20 toluene/ethanol solution at 25°C.

In one embodiment, the solid pharmaceutical compositions of the present invention comprise about 25-35% of corticosteroid crystals, microencapsulated with a taste-masking layer comprising a water-insoluble polymer (e.g., ethylcellulose); about 60-70% of rapidly-dispersing granules (e.g., comprising crospovidone and mannitol); about 5% of additional disintegrant (e.g., crospovidone); about 1% of one or more flavors, and about 0.5%-1% of a sweetener (e.g., sucralose).

The method of producing drug-layered beads in one embodiment of the invention comprises dissolving or suspending corticosteroid in a polymeric binder solution and layering onto inert particles (50-100 mesh or 150-300 μm in diameter) such as sugar spheres or cellulose spheres (e.g., Celphere® CP-203) using a fluid-bed coater equipped with a bottom-spray Wurster insert. These corticosteroid-coated

beads can then be taste-masked by fluid-bed coating or by solvent coacervation as described herein.

In another embodiment, the compositions of the present invention can comprise corticosteroid particles (e.g., crystals), coated with a taste-masking layer.

- 5 The taste-masking layer (as described herein) can be applied to the corticosteroid particles by any suitable method, for example coacervation or fluidized bed coating methods. Alternatively, the compositions of the present invention can comprise a corticosteroid complexed with a cyclodextrin.

- 10 In one embodiment, the method of preparing the compositions of the present invention includes a taste-masking step. The taste-masked corticosteroid-containing particles of the compositions of the present invention (e.g., corticosteroid crystals, corticosteroid-containing microgranules or drug-layered beads) of the present invention can be prepared by various methods, including solvent coacervation with a water-insoluble polymer such as ethylcellulose. The water-insoluble polymer (e.g.,
15 ethylcellulose), a phase-inducer (e.g., polyethylene), and corticosteroid are loaded into a coacervation tank containing cyclohexane. The mixture in the tank is heated to about 80°C to dissolve the ethylcellulose, and then slowly cooled under controlled conditions thereby causing phase-induced microencapsulation of corticosteroid particles by the ethylcellulose. Microencapsulation or coacervation refers to the
20 process of applying a membrane by phase separation for imparting taste-masking (or sustained release) properties. Upon reaching ambient temperature, the suspension of microencapsulated corticosteroid particles are filtered, washed with fresh cyclohexane and dried to reduce residual solvent levels within acceptable limits (e.g., <4,000 ppm), in one embodiment less than 1,000 ppm. The coating weight of the microencapsulated
25 corticosteroid particles can range from about 5% to about 30% including about 10%, 15%, 20%, and 25%, inclusive of all ranges and subranges therebetween. Examples of such a coacervation process are disclosed in U.S. Pat. Nos. 5,252,337, 5,639,475, 6,139,865 and 6,495,160.

- 30 Alternatively, the coacervation solution can comprise a mixture of the water-insoluble polymer (e.g., ethylcellulose) and a water-insoluble or gastrosoluble pore-former (e.g., calcium carbonate). The ratio of water-insoluble polymer to pore-former can range from about 50/50 to 95/05, including about 55/45, about 60/40, about 65/35, about 70/30, about 75/25, about 80/20, about 85/15, and about 90/10, including

all ranges and subranges therebetween. The coating weight of the microencapsulated corticosteroid particles can range from about 5% to about 30% including about 10%, 15%, 20%, and 25%, inclusive of all ranges and subranges therebetween. In one embodiment, the coacervation step comprises suspending the drug-containing
5 particles in a solution of water-insoluble ethylcellulose at 80°C in the coacervation tank. During the cooling cycle, the micronized pore-former is introduced into the tank at a temperature of about 58°C, while constantly stirring the suspension to uniformly distribute the pore-former in the microcapsule-membrane, at the forming/hardening phase. Examples of such a coacervation process are disclosed in U.S. Patent
10 Publication No. US 2006/0105038.

In one embodiment, the solid pharmaceutical composition of the present invention is in the form of an orally disintegrating tablet (ODT). In one such embodiment the ODT comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid, and the rapidly dispersing
15 granules comprise a disintegrant and a sugar alcohol and/or saccharide. The drug particles may comprise, for example, corticosteroid crystals with or without a coating, corticosteroid-layered beads or granulates of corticosteroid with one more additional components. In certain embodiments the ODT is in the form of a wafer or film (for example those described in US 6,534,549, US 7,125,564, etc.).

20 In one embodiment of the present invention the solid composition comprises a lyophilized matrix, wherein the lyophilized matrix comprises corticosteroid and an excipient. Suitable excipients include mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

The amount of corticosteroid-containing granules in the solid compositions of
25 the present invention can range from about 5% to about 50%, including about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, and about 50%, inclusive of all values, ranges, and sub-ranges therebetween. In one embodiment, the composition of the present invention is an ODT comprising about 30% by weight of corticosteroid-containing granules.

30 One embodiment of a method for producing pleasant tasting corticosteroid ODT formulations of the present invention, comprising corticosteroid microparticles with a mean particle size of about 100-400 μm , comprises (i) preparing drug-

containing cores having corticosteroid crystals with a desired mean particle size, e.g., as microgranules, corticosteroid particles (e.g., crystals), or as drug-layered beads, (ii) preparing granules comprising a disintegrant, a sugar alcohol and/or a saccharide, and (iii) compressing a blend comprising the corticosteroid microparticles and the
5 disintegrant granules, optionally with pharmaceutically acceptable flavorant(s), sweetener(s), other disintegrant(s), colorant(s) and/or compression aides such as microcrystalline cellulose in sufficient quantities into the ODT form using a tablet press, such as a rotary tablet press equipped with an external lubrication system to lubricate the punches and dies prior to compression. These ODT tablets rapidly
10 disintegrate upon exposure to the saliva in the mouth into a smooth, easy-to-swallow suspension with no gritty aftertaste.

In another embodiment, the method for preparing ODT formulations of the present invention comprising corticosteroid microparticles with a mean particle size of about 100-400 μm can also include a unit process for taste-masking the
15 corticosteroid-containing particles (e.g., corticosteroid crystals, corticosteroid-containing granules or drug-layered beads) by coacervation or fluid bed coating prior to blending and compression into ODT tablets. For example, corticosteroid crystalline material with an average particle size range of about 1-200 μm , more particularly about 50-150 μm can be coated with a taste-masking layer by either fluid-bed coating
20 or solvent coacervation in accordance with other aspects of the invention. Corticosteroid crystalline material with a mean particle size of about 5-50 μm can also be taste-masked by solvent coacervation as described herein.

In another embodiment, the compositions of the present invention can be orally disintegrating tablets prepared by mixing corticosteroid microgranules or taste-
25 masked corticosteroid microparticles, one or more flavoring agents, a sweetener, rapidly-dispersing microgranules, microcrystalline cellulose, and an additional disintegrant, and compressing this mixture into orally disintegrating tablets. The orally disintegrating tablets formed thereby rapidly disintegrate on contact with saliva in the buccal cavity, and have a pleasant taste (good creamy mouth feel) and provide
30 rapid, substantially-complete release of the dose in the stomach.

In yet another embodiment, the compositions of the present invention may be orally disintegrating tablets formed by compressing a composition comprising corticosteroid-containing particles, rapidly-dispersing granules, and optionally

flavoring agents, sweeteners, and other pharmaceutically acceptable excipients in a tablet press equipped with an externally lubricating system to pre-lubricate dies and punches, thereby providing a tablet formulation otherwise free of lubricant. The orally disintegrating tablets thus produced typically exhibit sufficient hardness and

5 sufficiently low friability to be suitable for packaging in HDPE bottles and push-through film backed or peel-off paper backed blister packs using conventional equipment for storage, transportation and commercial distribution.

In another embodiment, a method of manufacturing orally disintegrating tablets of the present invention comprises the following steps: (a) preparing

10 corticosteroid-containing microgranules by granulating crystalline corticosteroid material having an average particle size of about 5-50 μm and one or more diluents/fillers such as lactose, mannitol, microcrystalline cellulose and mixtures thereof, with a polymeric binder in a high-shear granulator or a fluid-bed coater; (b) granulating one or more sugar alcohols and/or saccharides, each having an average

15 particle diameter of not more than about 30 μm , with a disintegrant such as crospovidone, using water or an alcohol-water mixture in a conventional granulator, and drying the granulate in fluid-bed equipment or a conventional oven to produce rapidly-dispersing microgranules with an average particle size of not more than about 400 μm , as described in U.S. Patent Publication No. US 20050232988; filed Apr. 19,

20 2004; (c) blending the corticosteroid microgranules of step (a) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and the rapidly-dispersing microgranules of step (b); and (d) compressing the blend of step (c) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre-lubricate the dies and punches.

25 In another embodiment, a method of manufacturing orally disintegrating tablets of the present invention comprises the following steps: a) preparing a drug-containing core particle (e.g., corticosteroid crystals, drug-layered beads, or corticosteroid-containing microgranules) by granulating the drug and optionally one or more diluents/fillers such as lactose, mannitol, microcrystalline cellulose and

30 mixtures thereof with a polymeric binder in a high-shear granulator or a fluid-bed coater, or drug-layering on an inert particle (60-100 mesh sugar sphere or cellulose sphere, e.g., Celphere® CP-203) from a solution/suspension comprising a polymeric binder and the drug in a fluid-bed coater and optionally applying a seal-coat (e.g.,

Opadry® Clear); b) taste-masking core particles by microencapsulation, e.g. by solvent coacervation or fluid-bed coating with a water-insoluble polymer such as ethylcellulose, or with a mixture of a water-insoluble functional polymer and a water-soluble/gastrosoluble pore-former (e.g., ethylcellulose and sodium chloride or calcium carbonate at a ratio ranging from about 50/50 to 95/5) to produce pleasant-tasting microparticles with a desired particle size distribution (e.g., an average particle size of not more than about 400 µm, or an average particle size of not more than about 300 µm); c) granulating one or more sugar alcohols and/or saccharides, each of which has an average particle diameter of not more than about 30 µm, with a disintegrant such as crospovidone, as disclosed herein; d) blending the taste-masked microparticles of step (b) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and rapidly-dispersing microgranules of step (c); and e) compressing the blend of step (d) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre-lubricate the dies and punches.

EXAMPLE 1

Fluticasone Propionate Microgranules A: Mannitol 25 (91.2% w/w) and Crospovidone XL-10 (4.8% w/w) at a ratio of 95/5 are co-milled individually by passing the mixture through a Comil® milling apparatus, equipped with 0.225" spacers, at a speed of about 1400-1500 rpm. The mannitol, crospovidone, and fluticasone propionate (4% w/w) crystalline material are blended for about 3-5 minutes to mix the ingredients. A Glatt GPCG-3 fluid-bed apparatus equipped with a top spray granulation chamber and a granulation bowl is charged with the pre-blend of mannitol, crospovidone, and fluticasone propionate (batch size: 1500 g) and granulated by spraying purified water (nozzle: 1.2 mm tip) at an atomization pressure of about 1.25 bar and at a spray rate of 30-50 mL/min and an outlet temperature of >70°C and at a product temperature of >33°C. The wet mass is dried until the moisture level (the percent loss on drying) is less than about 1%.

Tableting: A Hata production tablet press equipped with a vacuum transfer system, tablet de-duster, a metal detector, and a Matsui Ex-lube system were set up according to standard operating procedures. Magnesium stearate was used as a processing aid, i.e., to externally lubricate the punch and die surfaces and was

therefore present in only trace amounts on the tablets. The weight range for the tablets was typically $\pm 5\%$ of the target tablet weight. The Ex-lube system was started to ensure that the lubricant was spraying properly when the tablet press was running. The tableting parameters, such as fill depth (mm), pre-compression position (mm or kN) and main compression position (mm or kN) were adjusted on the press in order to produce 4 mg tablets that meet the exemplary specifications listed below:

TABLE: Tablet Parameters

Parameter	Target	Range
Weight (mg)	100	95-105
Thickness (mm)	2.4	2.0-2.8
Hardness (N)	28	8-48
Friability	NMT 0.6%	1.0%
Weight 10 tablets (g)	1.0g	0.96-1.04

Following the successful set-up, the press was run in 'Automatic Mode' until completion. During the run, tablets were sampled periodically to ensure that the tablets produced would meet the specifications listed above.

The tablets are tested in the USP <701> Disintegration test and disintegrate in about 60 seconds or less.

EXAMPLE 2

A liquid is prepared by mixing 89.8% of 95% ethanol, by weight 5% ethylcellulose, 0.2% by weight oleic acid and 5% fluticasone propionate. Upon dabbing on to a mucosal surface a film is formed which adheres readily to skin or mucosal tissues.

An ethyl alcohol based gel is prepared by mixing the following components: 67% by weight of 95% ethyl alcohol; 8% by weight ethylcellulose; 2% by weight hydroxypropylcellulose; 2% by weight polyacrylic acid; 14% by weight menthol; 5% by weight water USP; and 2% by weight fluticasone propionate. A smooth, slightly opaque and sticky gel is formed.

The film, resulting from the application of this gel to a mucosal surface adheres to the surface and requires mechanical effort for its removal.

It will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be
5 made without departing from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

WHAT IS CLAIMED IS:

1. A solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.
2. The solid pharmaceutical composition of claim 1, wherein said solid pharmaceutical composition disintegrates within 30 seconds.
3. The solid pharmaceutical composition of claim 1, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, and salts, solvates and esters thereof.
4. The solid pharmaceutical composition of claim 1, further comprising an adhesive agent.
5. The solid pharmaceutical composition of claim 4, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyacrylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.
6. The solid pharmaceutical composition of claim 1, further comprising a disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxypropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

7. The solid pharmaceutical composition of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.
8. The solid pharmaceutical composition of claim 1, which is substantially free of lubricant.
9. The solid pharmaceutical composition of claim 1, further comprising at least one antifungal agent.
10. The solid pharmaceutical composition of claim 9, wherein the antifungal agent is selected from the group consisting of mitotic inhibitor antifungals, pyrimidine analog antifungals, polyene antifungals, benzimidazole antifungals, imidazole antifungals, polyene antifungals, triazole antifungals, thiazole antifungals, allylamine antifungals, echinocandin antifungals, and uncategorized antifungals.
11. The solid pharmaceutical composition of claim 10, wherein the antifungal agent is selected from the group consisting of anidulafungin, caspofungin, clotrimazole, fluconazole, itraconazole, micafungin, nystatin, posaconazole, and voriconazole.
12. The solid pharmaceutical composition of claim 1, further comprising at least one antiviral agent.
13. The solid pharmaceutical composition of claim 12, wherein the antiviral agent is selected from the group consisting of interferons, nucleoside and nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, fusion inhibitors, maturation inhibitors, puridine analogs, pyrimidine analogs, and uncategorized antiviral drugs.
14. The solid pharmaceutical composition of claim 12, wherein the antiviral agent is selected from the group consisting of aciclovir, brivudine, docosanol, famciclovir, ganciclovir, idoxuridine, penciclovir, trifluridine, tromantadine, valaciclovir, and valganciclovir.
15. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in the form of an orally disintegrating tablet (ODT).

16. The pharmaceutical composition of claim 15, wherein the ODT comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid, and the rapidly dispersing granules comprise a disintegrant and a sugar alcohol and/or saccharide.
17. The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .
18. The pharmaceutical composition of claim 16, wherein the drug particles have an average particle size of less than about 4 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .
19. The pharmaceutical composition of claim 16, wherein the corticosteroid is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .
20. The pharmaceutical composition of claim 4, wherein the adhesive agent and the corticosteroid are intimately associated.
21. The pharmaceutical composition of claim 20, wherein said corticosteroid is surrounded or encapsulated by the adhesive agent.
22. The pharmaceutical composition of claim 20, wherein the corticosteroid is disposed on the surface of said adhesive agent.
23. The pharmaceutical composition of claim 16, wherein the ODT comprises a lyophilized matrix, wherein the lyophilized matrix comprises the corticosteroid in combination with at least one excipient.
24. The pharmaceutical composition of claim 23, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

25. The pharmaceutical composition of claim 23, wherein the ODT is in the form of a wafer or film.
26. The pharmaceutical composition of claim 16, wherein the ODT is in the form of a wafer or film.
27. An orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid selected from the group consisting of fluticasone, budesonide, mometasone, and salts, solvates and esters thereof, wherein the orally disintegrating tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.
28. The orally disintegrating tablet of claim 27, wherein the orally disintegrating tablet comprises about 0.05-0.3 mg fluticasone.
29. A method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1.
30. The method of claim 29, wherein said inflammation of the gastrointestinal tract comprises inflammation of the esophagus.
31. The method of claim 29, wherein said condition is eosinophilic esophagitis.
32. The method of claim 29, wherein said inflammation comprises inflammation of the glottis, epiglottis, tonsils, or oropharynx.
33. The method of claim 29, wherein said condition is viral or bacterial pharyngitis.
34. The method of claim 29, wherein said condition is gastroesophageal reflux disease (GERD), nonerosive reflux disease (NERD) or erosive esophagitis.
35. A substantially non-aqueous liquid pharmaceutical composition comprising a corticosteroid and a pharmaceutically acceptable liquid.
36. The liquid pharmaceutical composition of claim 35 wherein the liquid is selected from the group consisting of pharmaceutically acceptable alcohols, oils, glycols, glycol ethers, pyrrolidones, polyethylene glycols, N-methyl-2-pyrrolidone, 2-pyrrolidone,

glycerol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, ethyl butyrate, dibutyl malonate, tributyl citrate, tri-n-hexyl acetylcitrate, diethyl succinate, diethyl glutarate, diethyl malonate, triethyl citrate, triacetin, tributyrin, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, caprolactam, N,N-diethyl-m-toluamide, 1-dodecylazacycloheptan-2-one, 1,3-dimethyl-3,4,5,6-tetrahydro-2(1H)-pyrimidinone, and combinations thereof.

37. The liquid pharmaceutical composition of claim 36 wherein the liquid is selected from the group consisting of alcohols, oils; glycols; glycol ethers; pyrrolidones; polyethylene glycols, glycerol and combinations thereof.
38. The liquid pharmaceutical composition of claim 37 wherein the liquid is selected from the group consisting of ethanol, glycerol, propylene glycol, glycerides, polyethylene glycol with a molecular weight between about 200 and 600, and combinations thereof.
39. The liquid pharmaceutical composition of claim 35, further comprising a phase change agent dissolved or suspended in said liquid, wherein after administration to a patient, said composition undergoes a change in physical properties of the composition upon contact with the gastrointestinal tract of said patient, whereby contact of the corticosteroid with the gastrointestinal tract of the patient is enhanced and/or prolonged.
40. The liquid pharmaceutical composition of claim 39, wherein after administration to a patient, said composition precipitates onto the mucosa of the gastrointestinal tract of the patient, whereby deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.
41. The liquid pharmaceutical composition of claim 39, wherein after administration to a patient, said composition forms a gel on contact with the mucosa of the gastrointestinal tract of the patient, whereby the deposition of the corticosteroid onto the mucosa of the gastrointestinal tract is enhanced and/or prolonged.
42. The liquid pharmaceutical composition of claim 35, wherein after administration to a patient, said composition increases in viscosity upon contact with the mucosa of the

- gastrointestinal tract of the patient, whereby the residence time of the corticosteroid on the mucosa of the intestinal tract is prolonged.
43. The liquid pharmaceutical composition of claim 39, wherein said phase change agent is a poorly water-soluble polymer.
 44. The liquid pharmaceutical composition of claim 39, wherein said phase change agent is a thermosensitive polymer whose aqueous viscosity changes in the range of about 15 – 40°C.
 45. The liquid pharmaceutical composition of claim 39, wherein said phase change agent increases in viscosity upon contact with the fluids of the oropharynx..
 46. The liquid pharmaceutical composition of claim 39, wherein the phase change agent is a polymer selected from the group consisting of poly(N-isopropylacrylamide), poly(ethylene glycol-(DL-lactic acid-co-glycolic acid)-ethylene glycol) and mixtures thereof.
 47. The pharmaceutical composition of claim 35, wherein said corticosteroid is selected from the group consisting of budesonide, fluticasone, flunisolide, ciclesonide, mometasone, tixocortol, beclomethasone, and salts, solvates, and esters thereof.
 48. The pharmaceutical composition of claim 41, wherein said liquid is water-miscible and said phase change agent is a bio-gelling polymer having a low water-solubility.
 49. The pharmaceutical composition of claim 48, wherein said water-miscible solvent is selected from the group consisting of ethanol, isopropyl alcohol, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol, propylene glycol, polyethylene glycol, tetraglycol, glycerol formal, solketal, ethyl acetate, ethyl lactate, diethyl carbonate, propylene carbonate, acetone, methyl ethyl ketone, dimethyl sulfoxide, dimethyl sulfone, tetrahydrofuran, and combinations thereof.
 50. The pharmaceutical composition of claim 48, wherein said bio-gelling polymer is selected from the group consisting of polylactides, polyglycolides, polycaprolactones, polydioxanones, polycarbonates, polyhydroxybutyrates, polyalkylene oxalates, polyanhydrides, polyamides, polyesteramides, polyurethanes, polyacetals, polyketals, polyorthocarbonates, polyphosphazenes, polyhydroxyvalerates, polyalkylene

succinates, poly(malic acid), poly(amino acids), chitin, chitosan, polyorthoesters, cellulose derivatives, cellulose esters, methacrylic acid and methacrylate polymers, and copolymers, terpolymers and mixtures thereof.

51. The pharmaceutical composition of claim 51, wherein said bio-gelling polymer is ethylcellulose.
52. The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 50%.
53. The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 100%.
54. The pharmaceutical composition of claim 45, wherein said increase in viscosity is at least 200%.

ABSTRACT

The present invention is directed to orally administered corticosteroid compositions. The present invention also provides a method for treating a condition associated with inflammation of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.