

AFFIDAVIT OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. I make this declaration of my own personal knowledge.
2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.
3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.
4. The archived data made viewable and browsable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.
5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]` aka an "extended URL". Thus, the extended URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.
6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.

7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 07/20/2022

Nathaniel E Frank-White
Nathaniel E Frank-White

EXHIBIT A

<https://web.archive.org/web/20140712140946/https://clinicaltrials.gov/ct2/show/NCT02045277>

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"

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Text Size

Safety and Efficacy of IDP 118 in the Treatment of Plaque Psoriasis

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified April 2014 by Valeant Pharmaceuticals International, Inc.

Sponsor:

Valeant Pharmaceuticals International, Inc.

Collaborator:

Dow Pharmaceutical Sciences

Information provided by (Responsible Party):

Valeant Pharmaceuticals International, Inc.

ClinicalTrials.gov Identifier:

NCT02045277

First received: January 22, 2014

Last updated: April 30, 2014

Last verified: April 2014

[History of Changes](#)

[Full Text View](#)

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[No Study Results Posted](#)

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[How to Read a Study Record](#)

Purpose

The objective of the study is to evaluate the safety and efficacy of a topical lotion when applied once daily to adult subjects with moderate to severe plaque psoriasis.

Condition	Intervention	Phase
Plaque Psoriasis	Drug: IDP 118 Lotion Drug: IDP-118 Monad HP 0.01% Lotion Drug: IDP-118 Monad Taz 0.045% Lotion Drug: IDP-118 Vehicle Lotion	Phase 2

Study Type: Interventional

Study Design: Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Factorial Assignment

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Phase 2, Multicenter, Double-Blind, Randomized, Vehicle Controlled Clinical Study to Assess the Safety and Efficacy of IDP 118 in the Treatment of Plaque Psoriasis

Resource links provided by NLM:

[MedlinePlus](#) related topics: [Psoriasis](#)

[U.S. FDA Resources](#)

Further study details as provided by Valeant Pharmaceuticals International, Inc.:

Primary Outcome Measures:

- The percent of subjects who experience a local skin reaction graded at a level of 3 at any point in the study [Time Frame: up to 3 months]
[Designated as safety issue: Yes]
- The percent of subjects with at least a 2-grade improvement from Baseline in the score for each of the signs of psoriasis [Time Frame: Up to 3 months]
[Designated as safety issue: No]

Estimated Enrollment: 210

Study Start Date: February 2014

Estimated Study Completion Date: November 2014

Estimated Primary Completion Date: November 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: IDP-118 Lotion halobetasol propionate [HP] 0.01%, tazarotene [Taz] 0.045%	Drug: IDP-118 Lotion
Active Comparator: IDP-118 Monad HP 0.01% Lotion HP 0.01%	Drug: IDP-118 Monad HP 0.01% Lotion Active Comparator

Active Comparator: IDP-118 Monad Taz 0.045% Lotion Taz 0.045%	Drug: IDP-118 Monad Taz 0.045% Lotion Active Comparator
Placebo Comparator: IDP-118 Vehicle Lotion Vehicle	Drug: IDP-118 Vehicle Lotion Vehicle

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Key Inclusion Criteria:

- Male or female, of any race, at least 18 years of age (inclusive).
- Freely provides both verbal and written informed consent.
- Has an area of plaque psoriasis appropriate for topical treatment that covers a BSA of at least 3%, but no more than 12%. The face, scalp, palms, soles, axillae and intertriginous areas are to be excluded in this calculation.
- Is willing and able to avoid prolonged exposure of the treatment area to ultraviolet radiation (natural and artificial) for the duration of the study.
- Has a clinical diagnosis of psoriasis at the Baseline visit with an IGA score of 3 or 4. (The face, scalp, palms, soles, axillae and intertriginous areas are to be excluded in this assessment, if psoriasis is present).

Key Exclusion Criteria:

- Has spontaneously improving or rapidly deteriorating plaque psoriasis or pustular psoriasis, as determined by the investigator.
- Presents with psoriasis that was treated with prescription medication and failed to respond to treatment, even partially or temporarily, as determined by the investigator.
- Presents with any concurrent skin condition that could interfere with the evaluation of the treatment areas, as determined by the investigator.
- Is pregnant, nursing an infant, or planning a pregnancy during the study period.
- Has received treatment with any investigational drug or device within 60 days or 5 drug half lives (whichever is longer) prior to the Baseline visit, or is concurrently participating in another clinical study with an investigational drug or device.

► Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02045277

Contacts

Contact: Binu J Alexander, MD 908-927-1756 binu.alexander@valeant.com

Locations

United States, California

Valeant Site 13 **Recruiting**
 Encino, California, United States, 91436

Valeant Site 11 **Not yet recruiting**
 San Diego, California, United States, 92123

Valeant Site 15 **Recruiting**
 Santa Rosa, California, United States, 95403

United States, Georgia

Valeant Site 10 **Recruiting**
 Augusta, Georgia, United States, 30909

Valeant Site 09 **Recruiting**
 Newnan, Georgia, United States, 30263

United States, Kentucky

Valeant Site 08 **Recruiting**
 Louisville, Kentucky, United States, 40217

United States, Maryland

Valeant Site 04 **Not yet recruiting**
 Rockville, Maryland, United States, 20850

United States, Michigan

Valeant Site 14 **Recruiting**
 Clinton Twp, Michigan, United States, 48038

United States, Minnesota

Valeant Site 07 **Not yet recruiting**
 Fridley, Minnesota, United States, 55432

United States, New Jersey

Valeant Site 01 **Recruiting**
East Windsor, New Jersey, United States

United States, New York

Valeant Site 03 **Recruiting**
New York, New York, United States, 10075

Valeant Site 17 **Not yet recruiting**
Rochester, New York, United States, 14623

United States, North Carolina

Valeant Site 02 **Not yet recruiting**
High Point, North Carolina, United States, 27262

United States, Texas

Valeant Site 05 **Recruiting**
Austin, Texas, United States, 78759

Valeant Site 06 **Not yet recruiting**
College Station, Texas, United States, 77845

United States, Utah

Valeant Site 16 **Recruiting**
Salt Lake City, Utah, United States, 84117

United States, Virginia

Valeant Site 18 **Not yet recruiting**
Lynchburg, Virginia, United States, 24501

Valeant Site 12 **Recruiting**
Norfolk, Virginia, United States, 23507

Sponsors and Collaborators

Valeant Pharmaceuticals International, Inc.

Dow Pharmaceutical Sciences

 More Information

No publications provided

Responsible Party: Valeant Pharmaceuticals International, Inc.
ClinicalTrials.gov Identifier: [NCT02045277](#) [History of Changes](#)
Other Study ID Numbers: V01-118A-201
Study First Received: January 22, 2014
Last Updated: April 30, 2014
Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:
Psoriasis
Skin Diseases, Papulosquamous
Skin Diseases

ClinicalTrials.gov processed this record on July 10, 2014

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JURAT

State/Commonwealth of VIRGINIA)

☐ City ☒ County of Roanoke County

On 07/20/2022, before me, Alexander Luis Marin
Date *Notary Name*

the foregoing instrument was subscribed and sworn (or affirmed) before me by:

Nathaniel E Frank-White

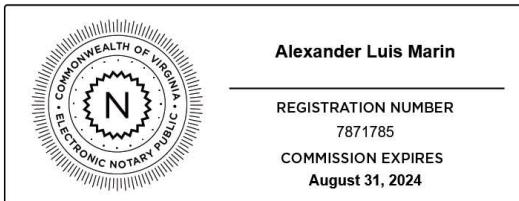
Name of Affiant(s)

☐ Personally known to me -- OR --

☐ Proved to me on the basis of the oath of _____ -- OR --
Name of Credible Witness

☒ Proved to me on the basis of satisfactory evidence: driver_license
Type of ID Presented

WITNESS my hand and official seal.



Notary Public Signature: Alexander Luis Marin

Notary Name: Alexander Luis Marin

Notary Commission Number: 7871785

Notary Commission Expires: 08/31/2024

Notarized online using audio-video communication

DESCRIPTION OF ATTACHED DOCUMENT

Title or Type of Document: Affidavit of Nathaniel E Frank-White

Document Date: 07/20/2022

Number of Pages (including notarial certificate): 8