guidance.html or *http://www.regulations.gov*.

Dated: December 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29742 Filed 12–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0365] (formerly Docket No. 2007D–0117)

Guidance for Industry on Orally Disintegrating Tablets; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Orally Disintegrating Tablets.'' The guidance provides pharmaceutical manufacturers of new and generic products with an agency perspective on the definition of an orally disintegrating tablet (ODT) and also provides recommendations to applicants who would like to designate proposed products as ODTs.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Frank O. Holcombe, Jr., Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Orally Disintegrating Tablets.'' The guidance provides pharmaceutical manufacturers of new and generic drug products with an agency perspective on the definition of an ODT and also provides recommendations to applicants who would like to designate proposed products as ODTs.

On April 9, 2007 (72 FR 17563), FDA announced the availability of the draft version of this guidance. The public comment period closed on June 8, 2007. The draft guidance also was discussed at an Advisory Committee for Pharmaceutical Science meeting held on July 22 and 23, 2008. A number of comments were received from the public and during the meeting, all of which the agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

In an effort to develop drug products that are more convenient to use and to address potential issues of patient compliance for certain product indications and patient populations, pharmaceutical manufacturers have developed products that can be ingested simply by placing them on the tongue. The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need to chew the tablet, swallow an intact tablet, or take the tablet with liquids. This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders).

As firms started developing additional products using different technology and formulations, many of these later products exhibited wide variation in product characteristics from the initial products. Because this shift in product characteristics can affect suitability for particular uses, the agency developed this guidance for industry.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on orally disintegrating tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: December 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29688 Filed 12–15–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0628]

Microbiological Testing for Contact Lens Care Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Microbiological Testing for Contact Lens Care Products.'' FDA is co-sponsoring the public workshop with the American Academy of Ophthalmology, the American Academy of Optometry, the American Optometric Association, and the Contact Lens Association of Ophthalmologists. The purpose of the public workshop is to discuss test method parameters for evaluating the activity of contact lens care products against *Acanthamoeba*

Dr. Falk Pharma **Ex. 1006**
IPR Petition USP 11,246,828