

[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 The draft guidance also was discussed at an Advisory Committee for Pharmaceutical Science meeting held on July 22 and 23, 2008.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*

and to discuss elements of microbiological test methods that simulate "real world" consumer use conditions.

**Date and Time:** The public workshop will be held on January 22 and 23, 2009, from 8 a.m. to 5 p.m. Participants are encouraged to arrive by 7:30 a.m. to allow enough time for parking and security screening. Security Screening will begin at 7 a.m.

**Location:** The public workshop will be held at the Food and Drug Administration, White Oak Conference Center, 10903 New Hampshire Ave., Bldg. 2 (Central Shared Use Building), Silver Spring, MD. Attendees should follow the directions provided in the *Registration Information* section of this document.

**Contact:** Daryl L. Kaufman, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4200, FAX: 240-276-4234, e-mail:

[Daryl.Kaufman@fda.hhs.gov](mailto:Daryl.Kaufman@fda.hhs.gov), or

Marc Robboy, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4200, FAX: 240-276-4234, e-mail: [Marc.Robboy@fda.hhs.gov](mailto:Marc.Robboy@fda.hhs.gov).

**Agenda:** The purpose of the conference is to discuss test methods for evaluating the anti-microbial activity of contact lens care products.

On January 22, 2008, we hope to reach consensus on critical test method parameters for evaluating the activity of contact lens care products against *Acanthamoeba*. These parameters include organism species and strain, trophozoite culture and cyst production, microbial challenge level, and assay method for survivors.

On January 23, 2008, we hope to present and discuss critical elements for new or modified disinfection efficacy test methods that simulate "real world" consumer use conditions. These elements include contact lens and lens case uptake of preservative and other solution ingredients, solution evaporation, minimal consumer compliance, biofilm formation and clinical isolates as challenge organisms.

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted on the Internet at [www.jcahpo.org/clmw](http://www.jcahpo.org/clmw).

**Registration Information:** Registration must be completed online at [www.jcahpo.org/clmw](http://www.jcahpo.org/clmw). Please pre-register no later than January 8, 2009 (see instructions in this paragraph). There will be no onsite registration.

Non-U.S. citizens are subject to additional security screening and should pre-register at least 3 weeks in advance. There is a registration fee of \$250 for this workshop. Early registration is recommended because seating is limited.

If you need special accommodations due to a disability, please contact Ms. Janice Prestwood at 800-284-3937, ext. 229 (toll free), 651-731-7229 (direct) or 651-731-0410 (fax) at least 7 days before the public workshop. Lodging, travel, and security clearance information are also available from the registration Web site. Persons without Internet access may contact Ms. Janice Prestwood for help in completing the registration form.

Dated: December 9, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-29741 Filed 12-15-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

**Name:** Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

**Dates and Times:** January 14, 2009, 11 a.m.-3 p.m.

**Place:** Teleconference meeting.

**Status:** The meeting will be open to the public; audio conference access limited only by availability of telephone ports.

**Purpose:** The Committee represents the required preliminary planning of the mandated ACICBL activities for the 2009 calendar year. The meeting will afford committee members with the opportunity to identify and discuss potential topics on interdisciplinary and community based trainings for the focus of the Ninth Annual ACICBL Report to the Secretary and Congress. The discussion will also include the identification of potential speakers with expertise on recommended topics for the Annual Report as well as strategies for moving forward. In addition, the Committee will finalize the dates, format, and agenda for the two remaining mandated meetings of the 2009 calendar year.

**Agenda:** The agenda includes a discussion of potential topics and speakers for the Ninth Annual ACICBL Report, and planning for the two remaining meetings of the 2009 calendar

year. Agenda items are subject to change as dictated by the priorities of the Committee.

**Supplementary Information:** The ACICBL will meet on Wednesday, January 14, 2009, 11 a.m. to 3 p.m. (EST) via telephone conference. To participate in this telephone conference call, please dial 1-888-272-7337 and provide the following information:

**Leader's Name:** Mr. Lou Coccodrilli.

**Passcode:** 9501090.

**For Further Information Contact:** Anyone requesting information regarding the Committee meeting should contact Lou Coccodrilli, Federal Official for the ACICBL, and Chief of the Area Health Education Center Branch, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; [lcoccodrilli@hrsa.gov](mailto:lcoccodrilli@hrsa.gov) or (301) 443-6590. CAPT Norma Hatot, Senior Nurse Consultant may also be contacted for inquiries via e-mail at [nhatot@hrsa.gov](mailto:nhatot@hrsa.gov) or telephone at (301) 443-2861.

Dated: December 9, 2008.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Service Administration

#### Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Request for Nominations

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill four upcoming vacancies on the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

**Authority:** 42 U.S.C. 294f, Section 756 of the PHS Act, as amended. The Advisory Committee is governed by provisions of Public Law (Pub. L.) 92-463, as amended (5 U.S.C. Appendix 2) which sets forth standards for the formation and use of advisory committees.

**DATES:** The Agency must receive nominations on or before January 16, 2009.

**ADDRESSES:** All nominations are to be submitted by mail to Louis D. Coccodrilli, Designated Federal Official, ACICBL, Division of Diversity and Interdisciplinary Education (DDIE), Bureau of Health Professions (BHPr), HRSA, Parklawn Building, Room 9-36, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** CAPT Norma J. Hatot, Senior Program Officer, DDIE, BHPr, via e-mail at