

## I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying contact cooling systems for aesthetic use into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)). The guidance document will serve as the special control for contact cooling systems for aesthetic use device. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act, request that FDA classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the time frames established by section 513(f)(2) of the FD&C Act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing the guidance as a final guidance document. Therefore, FDA is issuing the guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

## II. Significance of Guidance

The guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the Agency's current thinking on contact cooling systems for aesthetic use. 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 statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To

receive a hard copy of "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use," you may send a fax request to 301-847-8149. Please use the document number 1734 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR 812 have been approved under OMB control number 0910-0078; the collection of information 21 CFR 50.23 have been approved under OMB control number 0910-0586; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910-0119; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR 801 have been approved under OMB control number 0910-0485.

## V. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: February 1, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-2553 Filed 2-4-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0066]

### Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 8 and 9, 2011, from 8 a.m. to 6 p.m.

*Addresses:* FDA is opening a docket for public comment on this document. The docket will open for public comment on February 7, 2011, and will close on March 1, 2011. Interested persons are encouraged to use the docket to submit either electronic or written comments regarding this meeting. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

*Location:* Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6313, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory

committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On March 8 and 9, 2011, the committee will discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims. The scientific issues to be discussed include:

(1) The risks and benefits of making clinical genetic tests available for direct access by a consumer without the involvement of a clinician (*i.e.*, without a prescription). The discussion will include consideration of the benefits and risks of direct access for different tests or categories of tests that would support differences in the regulatory approach. Clinical genetic test categories that have been proposed to be offered directly to consumers include:

(a) Genetic carrier screening for hereditary diseases (*e.g.*, cystic fibrosis carrier screening);

(b) Genetic tests to predict risk for future development of disease, in currently healthy persons (*e.g.*, tests to predict risk of developing breast or ovarian cancer); and

(c) Genetic tests for treatment response prediction (*e.g.*, tests to predict whether individual will respond to a specific drug).

(2) The risks of and possible mitigations for incorrect, miscommunicated, or misunderstood test results for clinical genetic tests that might be beneficial if offered through direct access testing.

(3) The level and type of scientific evidence appropriate for supporting direct-to-consumer genetic testing claims including whether it should be different than that required to support similar claims for prescription use clinical genetic tests.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views,

orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 23, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. immediately following lunch on March 8 and 9. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 15, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 16, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, Food and Drug Administration, at 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 2, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Anti-Infective Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Anti-Infective Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 5, 2011, from 8:30 a.m. to 4 p.m.

*Location:* Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

*Contact Person:* Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: [minh.doan@fda.hhs.gov](mailto:minh.doan@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On April 5, 2011, the committee will discuss new drug application (NDA) 20-1699, for FIDAXOMICIN tablets, submitted by Optimer Pharmaceuticals, Inc., for the requested indication of treatment of adults with *Clostridium difficile* infection (CDI), also known as *Clostridium difficile*-associated diarrhea (CDAD), and prevention of recurrences.

FDA intends to make background material available to the public no later than 2 business days before the meeting.