§ 123.28(c), (d) Records—molluscan shellfish (see § 123.6(c)(7))

Dated: July 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18459 Filed 7–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic 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: Dermatologic and Ophthalmic 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 September 18 and 19, 2000, 8:30 a.m. to 5 p.m.

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

Contact: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18 and 19, 2000, the committee will discuss two new drug applications (NDA's): NDA 18–662, Accutane® (isotretinoin) capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne; and NDA 21–177, (new formulation) isotretinoin capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne.

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 by September 7, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 2000, 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.

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

Dated: July 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–18457 Filed 7–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1394]

Medical Devices; CLIA Waiver Criteria; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to review the criteria used to determine whether specific laboratory tests are waived from certain requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The purpose of the public workshop is to obtain additional comments on the criteria and process the agency should use to determine when a particular test is waived.

Date and Time: The public workshop will be held on August 14 and 15, 2000, from 9 a.m. to 5 p.m. each day.

Location: The public workshop will be held at the Washingtonian Center Marriott Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 301–590–0044.

Contact: Clara A. Sliva, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–827–0496, FAX 301–827–1401, e-mail: CAS@cdrh.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to the contact person by August 4, 2000. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20850, by September 14, 2000.

If you need special accommodations due to a disability, please contact Clara A. Sliva at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

A. Background

CLIA specifies that laboratory requirements be based on the complexity of the tests performed and establishes criteria for categorizing a test as waived. Responsibility for determining whether a particular test is waived was transferred from the Centers for Disease Control and Prevention (CDC) to FDA on January 31, 2000. In the **Federal Register** of September 13, 1995 (60 FR 47534), CDC published proposed clarifications to the statutory criteria for waiver. CDC based the proposal on guidelines CDC developed to assist the manufacturers in submitting waiver requests. The proposed regulations recommend a methodology for demonstrating that a test system proposed for waived status be so ''simple'' and ''accurate'' as to render the likelihood of erroneous results negligible. The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law No. 105–115) modified 42 U.S.C. 263a (d)(3) of the Public Health Service Act by adding the phrase ''by the user'' to clarify that waived tests include those which employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. FDAMA also clarified that waived tests include those that are cleared by FDA for home use.

Following transfer of responsibility for waiver determinations from CDC to FDA, manufacturers now submit premarket applications for products and requests for complexity categorization of these products to one agency. FDA is currently following the same policies applied by CDC to the waiver criteria prior to the transfer; FDA is performing the ''same work'' the ''same way.'' Under the current process, FDA generally will waive: (1) Any test system that meets the specifications described in the guidelines published in the proposed rule of September 13, 1995, and (2) any test system that provides scientifically valid data verifying that the statutory criteria for waiver have been met.