§ 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.

FDA believes it needs additional information from stakeholders to effectively implement its new responsibilities with respect to waiver decisions. In particular, the agency needs to decide whether to continue to apply the current criteria, finalize the proposed rule published by CDC in 1995, or repropose other procedures and criteria for this process. FDA is inviting laboratory groups, medical professional societies, patient groups, manufacturers, manufacturing associations, and other interested parties to attend this open public workshop regarding the criteria for waiver. To the extent possible, oral and written testimony should address the following general and specific questions:

B. General Questions for Public Input

Criteria for waived tests under the Public Health Service Act were amended by FDAMA to read: Waived tests ''are laboratory examinations and procedures that have been approved by Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that (A) employ methodologies that are so simple and accurate to render the likelihood of erroneous results by the user negligible, or (B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly * * *.''

1. What criteria should be used to demonstrate that a waived test is a simple laboratory examination and procedure with ''an insignificant risk of an erroneous result?'' For example:

a. Should a waived test, when performed by untrained users, provide an accurate result with no significant clinical or statistical error when compared to a measure of truth? This requires availability of well-characterized reference methods and/or materials as part of the waived test assessment. The current threshold for waiver as established by CDC is no significant inaccuracy and no significant imprecision.

b. Should a waived test, when performed by untrained users, provide a test result that shows no user error when compared to the same test performed in a CLIA certified lab by a trained user? This requires comparison of the test in a lay-user setting with performance of the test in a CLIA certified lab by a trained user. The threshold for waiver would be no difference in performance in the two settings.

c. Should FDA apply a different model to determine the waived status of a test?

2. What criteria should FDA use to determine if a methodology is ''so simple and accurate to render the likelihood of erroneous results by the user negligible?''

a. Should a waived test be so accurate when performed by untrained users that inaccurate results will not occur?

b. Should a waived test have variable accuracy if used adjunctively? Is it acceptable to waive tests that have inaccurate results but do not have any major negative clinical impact? How should FDA make this assessment?

3. What criteria should FDA use in determining that a test will ''pose no unreasonable risk of harm to the patient if performed incorrectly?''

4. Should the waiver process be different for screening tests that require a second test for confirmation? Because there are no CLIA standards for performance of waived testing, except instructions to follow the manufacturer's package insert, what is the assurance that confirmatory testing will be performed? Should the need for confirmatory testing raise, lower, or have no impact on the threshold for a waiver decision?

C. Specific Questions for Public Input

5. Should accuracy be determined using comparison of the waiver test to a well-characterized reference method and/or materials, to a designated comparative method and/or materials, to a working laboratory method and/or materials, to a clinical algorithm for diagnosis, and/or to other endpoints?

6. How many samples, what types of samples (real or artificial), by how many users and how many sites are appropriate to evaluate accuracy? (Current guidelines being followed by FDA are for performance to be demonstrated by laboratory users at a minimum of one site.)

7. What should be the background of these users?

8. What performance criteria (statistical or clinical) should FDA apply to the accuracy threshold for a waived test (e.g., t- test or McNemar test at key decision points, description of performance with confidence intervals at key decision points, use of set performance standards using a receiver operator curve–80 percent, 90 percent, 95 percent, or other–at key decision points, and/or others)?

9. How should FDA define precision for purposes of waiver determination? What types of samples, how many and what types of operators/sites are appropriate? Current CDC recommendation is for 20 samples at three levels representing appropriate decision points to be tested at three sites by lay users using materials in either artificial and/or real matrices depending on availability and biohazard issues.

10. What performance thresholds should FDA use to determine whether the precision studies are appropriate for waiver status (e.g., ANOVA (analysis of variance) analysis, use of a predefined performance goal, such as Tonks' formula, or percent agreement out of total repeat runs)?

11. What interference studies are appropriate to establish performance of waived tests (e.g., effects of hemolysis, lipemia, etc.)?

12. What environmental studies or flex (stress) studies are appropriate to establish performance of waived tests (e.g., temperature or humidity stresses, short fills)?

13. What additional studies (if any) should be submitted for evaluation of qualitative tests for waiver?

14. What additional studies (if any) should be submitted for evaluation of quantitative tests for waiver?

This will be an informal meeting conducted in accordance with 21 CFR 10.65.

Dated: July 14, 2000.

Lillian J. Gill,

Acting Deputy Director for Science, Center for Devices and Radiological Health.

[FR Doc. 00–18456 Filed 7–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301)443-7978.

National Cross-Site Assessment of the Addiction Technology Transfer Centers Network—(New)

The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) intends to conduct an assessment of its Addiction Technology Transfer Centers (ATTCs). The goal