

Dated: April 28, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-10361 Filed 5-3-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0199]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Procedures for the Clinical Laboratory Improvement Amendments of 1988 Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on administrative procedures for the Clinical Laboratory Improvement Amendments of 1988 (CLIA) categorization.

DATES: Submit written or electronic comments on the collection of information by July 6, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of

information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Administrative Procedures for CLIA Categorization—42 CFR 493.17 (OMB Control Number 0910-0607—Extension)

A guidance document entitled "Guidance for Administrative Procedures for CLIA Categorization" was released on May 7, 2008. The document describes procedures FDA will use to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer since the labeling (including operating instructions) is included in the 510(k) or PMA. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours	Total Operating & Maintenance Costs
42 CFR 493.17	60	15	900	1 hr	900 hr	\$46,800

¹ There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at \$52 per hour (52 x 900) totaling \$46,800. This includes the cost of copying and mailing

copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a

sponsor's categorization requests, and costs for basic office supplies (e.g. paper). The costs have been updated based on the Bureau of Labor Statistics estimates of inflation.

Dated: April 28, 2010.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Bariatric Surgery and Kidney Function.

Date: June 8, 2010.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: D.G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, pateldg@nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Collaborative Interdisciplinary.

Date: June 11, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: D.G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, pateldg@nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research;

93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 27, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-10268 Filed 5-3-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Drug Safety and Risk Management 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: Drug Safety and Risk Management 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 14, 2010, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland and University College (UMUC), The Ballrooms, 3501 University Blvd. East, Adelphi, MD. The conference center telephone number is 301-985-7300.

Contact Person: Elaine Ferguson, e-mail: elaine.ferguson@fda.hhs.gov (contact information through June 8, 2010, Elaine Ferguson c/o Melanie Whelan, Food and Drug Administration, 10903 New Hampshire Ave., WO51-6100, Silver Spring, MD 20993-0002, telephone: 301-827-7001, FAX: 301-847-8742), (contact information beginning June 9, 2010: Elaine Ferguson c/o Christine Shipe, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2419, Silver Spring, MD 20993-0002, telephone: 301-0796-9001, FAX: 301-847-8532), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512535. 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 September 14, 2010, the committee will discuss the abuse potential of the drug dextromethorphan and the public health benefits and risks of dextromethorphan use as a cough suppressant in prescription and nonprescription drug products. The Department of Health and Human Services received a request from the Drug Enforcement Administration for a scientific and medical evaluation and scheduling recommendation for dextromethorphan in response to the increased incidence of abuse, especially among adolescents.

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 August 30, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those desiring to make 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 August 20, 2010. 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 August 23, 2010.

Persons attending FDA's advisory committee meetings are advised that the