

**For Public**

*Toll Free Telephone:* (800) 779-1088

*Participant passcode:* 4863751

*Participant URL:* [https://](https://www.mymeetings.com/nc/join/)

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*Purpose:* The committee advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other federal, state, local and private agencies, and (b) establishment and maintenance of liaison with appropriate private entities, federal agencies, and state and local public health agencies with respect to smoking and health activities.

*Matters For Discussion:* The topic of the meeting is "50 Years of U.S. Tobacco Control" and will provide a review of the recently released Surgeon General's Report on the Health Consequences of Smoking—50 Years of Progress—leading to a discussion of what it will take to end the tobacco epidemic.

Agenda items are subject to change as priorities dictate.

*Contact Person For More Information:* Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the internet at [www.cdc.gov/tobacco](http://www.cdc.gov/tobacco) in mid-August or from Ms. Monica L. Swann, Management and Program Analyst, National Center for Chronic Disease Prevention and Health Promotion, CDC, 395 E. Street SW., Washington, DC 20024, telephone: (202) 245-0552.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Gary J. Johnson,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2014-09146 Filed 4-22-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Conducting Public Health Research in Thailand by the Ministry of Public Health (MOPH), Funding Opportunity Announcement (FOA) GH11-002; Conducting Public Health Research in China, FOA GH12-005, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act

(Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

*Time and Date:* 12:00 p.m.–5:00 p.m., May 14, 2014 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters For Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to "Conducting Public Health Research in Thailand by the Ministry of Public Health (MOPH), FOA GH11-002; and Conducting Public Health Research in China, FOA GH12-005, initial review."

*Contact Person For More Information:* Hylan Shoob, Scientific Review Officer, Center for Global Health (CGH) Science Office, CGH, CDC, 1600 Clifton Road, NE., Mailstop D-69, Atlanta, Georgia 30033, Telephone: (404) 639-4796. The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Gary J. Johnson,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2014-09148 Filed 4-22-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0079]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Generic Drug User Fee Act Cover Sheet

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 23, 2014.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written

comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0632. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Form FDA 3728, Animal Generic Drug User Fee Act Cover Sheet—21 U.S.C. 379j-21 (OMB Control Number 0910-0632)—Revision

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs, (2) annual fees for certain generic new animal drug products, and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the Animal Generic Drug User Fee Act (AGDUFA) Cover Sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

The Animal Generic Drug User Fee Amendments of 2013, signed by the President on June 13, 2013 (AGDUFA II) (Title II of Pub. L. 113-14), amended the FD&C Act authorizing FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. To implement changes under the reauthorization by their effective date of October 1, 2013, FDA sought and received OMB approval to update its Form FDA 3728 as described as follows:

On page 1 of the electronic questions under “Select an Application Type” users must select “Original” and then choose either, “Abbreviated New Animal Drug Application (ANADA)—under provisions of 512(b)(2) of FFDCA [the FD&C Act]” (21 U.S.C. 360b(b)(2)); or “Abbreviated New Animal Drug Application (ANADA)—for certain combination pioneer products approved under provisions of 512(d)(4) of FD&C Act.” If they select the first ANADA

type, they will be charge 100 percent of the application fee. If they select the second ANADA type, they will be charged at a rate of 50 percent of the original application fee. To facilitate the application process in this regard, on Form FDA 3728 we have added a line in section 3 that allows applicants to select the option, “3.2 Original Abbreviated New Animal Drug Application (ANADA)—for certain combination pioneer products approved

under provisions of section 512(d)(4) of the FD&C Act.”

In the **Federal Register** of February 18, 2014 (79 FR 9224), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3728 .....	20	2	40	.08 (4.8 minutes) .....	3.2

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are generic animal drug applicants. Based on data for the past 3 years, FDA estimates there are approximately 20 submissions annually and a total of 3.2 burden hours.

Dated: April 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-09201 Filed 4-22-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-N-0252]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification Requests and Recordkeeping

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by May 23, 2014.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:

202-395-7285, or emailed to [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0216. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Color Additive Certification Requests and Recordkeeping—21 CFR Part 80 (OMB Control Number 0910-0216)—Extension

We have regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are described in 21 CFR part 80. In the certification procedure, a representative sample of a new batch of

color additive, accompanied by a “request for certification” that provides information about the batch, must be submitted to FDA’s Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch. We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification.

Under § 80.21, a request for certification must include: Name of color additive, manufacturer’s batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person requesting certification. Under § 80.22, a request for certification must include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show: Name of color additive, manufacturer’s batch number and quantity, and name and address of person requesting certification. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all of the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The purpose for collecting this information is to help us assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The