

III. The Paperwork Reduction Act of 1995

This 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 (44 U.S.C. 3501–3520). In the guidance, FDA advises drug and medical device manufacturers who receive and use crude heparin to manufacture drugs and medical devices to notify the Agency of crude heparin found to contain any amount of OSCS, or to be derived from, in any amount, ruminant mucosa (unless approved in the drug or device application) (for human drugs, 21 CFR 314.81(b)(1)(ii); for animal drugs, 21 CFR 514.80(b); for medical devices, 21 CFR 803.50). The collections of information in 21 CFR 314.81(b)(1)(ii) have been approved under OMB control number 0910–0001; in 21 CFR 514.80(b) under OMB control number 0910–0284; and in 21 CFR 803.50 under OMB control number 0910–0437.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15100 Filed 6–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Tobacco Products Scientific 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: Tobacco Products Scientific 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 August 16, 2013, from 8:30 a.m. to 3 p.m.

Location: Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910.

Contact Person: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 5), email: TPSAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line, to learn about possible modifications before coming to the meeting.

Agenda: On August 16, 2013, the Committee will discuss possible approaches for evaluating information on the risks and potential benefits of a proposed modified risk tobacco product (MRTP) to the population as a whole. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a).

In reviewing MRTP applications, among other things, FDA must evaluate the effects of a proposed product on the health of individual tobacco users and the population as a whole, taking into account: (1) The relative health risks to individuals of the MRTP; (2) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the MRTP; (3) the increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP; (4) the risks and benefits to persons from the use of the MRTP compared to the use of smoking cessation drug or device products approved by FDA to treat nicotine dependence; and (5) comments, data, and information submitted to FDA by interested persons. 21 U.S.C. 387k(g)(4).

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 meeting 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 1, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. 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 July 25, 2013. 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 July 26, 2013.

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 Caryn Cohen 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: June 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-15102 Filed 6-24-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: "Health Care and Other Facilities"

OMB No. 0915-0309—Extension

Abstract: The Health Resources and Services Administration's Health Care and Other Facilities (HCOF) program provides congressionally-directed funds to health-related facilities for construction related activities and/or capital equipment purchases. Awarded facilities are required to provide a periodic (quarterly for construction related projects, annually for equipment only projects) update of the status of the funded project until it is completed. The monitoring period averages about three years, although some projects take up to five years to complete. The information collected from these updates is vital to program management staff to determine whether projects are progressing according to the established timeframes, meeting deadlines established in the Notice of Award, and drawing down

funds appropriately. The data collected from the updates are also shared with the Division of Grants Management Operations for their assistance in the overall evaluation of each project's progress.

An electronic form is currently being used for progress reporting for the HCOF program. This standardized form enables grantees to directly input the required information in a consistent and uniform manner. The electronic form minimizes burden to respondents by alerting the respondents when there are missing data elements prior to submission. We acknowledge a change in the burden estimate due to close out of old projects.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Construction Related	200	4	800	.5	400
Equipment Only	317	1	317	.5	158.5
Total	517		1,117		558.5

Dated: June 19, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013-15113 Filed 6-24-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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