

to have an accredited third party conduct a quality systems regulation inspection of their establishment instead of FDA, under the inspections by the Accredited Persons (AP) Program.

DATES: Submit either electronic or written comments on the collection of information by July 22, 2011.

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

Requests for Inspection Under the Inspection by Accredited Persons Program—21 U.S.C. 374(g) (OMB Control Number 0910-0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374 (g)). This amendment authorized FDA to establish a voluntary

third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled "Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007." This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm>. This guidance is intended to assist device establishments in determining whether they are eligible to participate in the AP Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 U.S.C. Section	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response (in hours)	Total hours
374(g)	100	1	100	15	1,500

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

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for

inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 100 of these manufacturers may use an AP in any given year.

Dated: May 12, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2010-N-0633]

Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of public workshop published in the **Federal Register** of January 7, 2011 (76 FR 1182). In that notice, FDA announced a public workshop that took place on February 15 and 16, 2011, and requested public comment regarding the topics discussed at the workshop on determining system attributes for tracking and tracing prescription drugs. The workshop provided a forum for discussing possible approaches to developing a track-and-trace system and for obtaining input from supply chain partners on potential attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages. FDA is reopening the comment period to allow additional time for interested persons both to consider all the information provided by the Agency related to the workshop and to submit additional comments.

DATES: Submit either electronic or written comments by June 22, 2011.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3100, connie.jung@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 7, 2011 (76 FR 1182), FDA published a notice announcing a public workshop entitled "Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop." In that notice, FDA requested the following: (1) Input and comments from interested stakeholders regarding possible approaches to developing a track-and-trace system and (2) input from supply chain partners on potential attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages.

Interested persons were originally given until April 16, 2011, to submit comments.

II. Request for Comments

On April 4, 2011, FDA posted on the FDA Web site a summary of the main

comments shared by the public workshop participants. To allow adequate time for interested persons both to consider all the information provided by the Agency related to the workshop and to submit additional comments, FDA is reopening the comment period.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Pulmonary-Allergy 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: Pulmonary-Allergy 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 June 23, 2011, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301-589-5200.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail:

PADAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 June 23, 2011, the committee will discuss the new drug application (NDA) 22150, icanitabant solution for injection (proposed trade name Firazyr), Shire Human Genetic Therapies, for the proposed indication of treatment of acute attacks of hereditary angioedema.

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 June 16, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. 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 June 8, 2011. 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