

to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

David S. Buckles, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G470, Silver Spring, MD 20993-0002, 301-796-5447.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance supersedes two previous guidance documents: “Medical Device Appeals and Complaints: Guidance for Dispute Resolution,” dated February 1998 and “Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA,” dated July 2001.

In the **Federal Register** of December 28, 2011 (76 FR 81511), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by April 26, 2012. In July 2012, section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360g-1) was added by section 603 of the FDA Safety and Innovation Act (FDASIA) (Pub. L. 112-114). FDA considered the public comments received and revised the guidance, as appropriate, and in accordance with the new requirements established by section 603 of FDASIA.

Section 517A includes new requirements pertaining to the process and timelines for appeals, made under 21 CFR 10.75 (10.75 appeal) of “significant decisions” regarding 510(k) premarket notifications, applications for premarket approval (PMAs), and applications for investigational device exemptions (IDEs). In this guidance document, the term “significant decision” refers to significant decisions pertaining to these submissions.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the

Agency’s proposed interpretation of this provision (for example, what constitutes a “significant decision”) in a draft guidance document entitled “Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A.”

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on CDRH’s Appeals Processes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

Guidance documents are also available at <http://www.regulations.gov>.

To receive “Center for Devices and Radiological Health Appeals Processes” you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1742 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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). The collections of information in the guidance document “Center for Devices and Radiological Health Appeals Processes” are approved under OMB control number 0910-0738. The guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR 10.30, 21 CFR 10.33, and 21 CFR 10.35 are approved under OMB control number 0910-0183; the collections of information in 21 CFR part 12 are approved under OMB control number 0910-0184; and the collections of information under 21 CFR part 900 are approved under OMB control number 0910-0309.

V. Comments

Interested persons may submit either written comments regarding this

document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: May 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-11706 Filed 5-16-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Anesthetic and Analgesic Drug Products 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: Anesthetic and Analgesic Drug Products 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 July 17, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, 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, email: AADPAC@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 July 17, 2013, the committee will discuss the safety and efficacy for the new drug application (NDA) 203077, proposed trade name MOXDUO (morphine sulfate and oxycodone hydrochloride) capsules, submitted by QRxPharma Inc., for the proposed indication of management of moderate to severe acute pain where the use of an opioid analgesic is appropriate. This product represents the first drug combination consisting of two immediate-release opioids.

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 July 2, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 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 24, 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 June 25, 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 Yvette Waples 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: May 13, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 07, 2013, 10:00 a.m. to 4:00 p.m. EDT.

Place: Audio Conference Call and Adobe Connect Pro.

The ACCV will meet on Friday, June 07 from 10:00 a.m. to 4:00 p.m. (EDT). The public can join the meeting by:

1. (Audio Portion) Calling the conference phone number 800-369-3104 and providing the following information:

Leaders Name: Dr. Vito Caserta
Password: ACCV

2. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: <https://hrs.connectsolutions.com/accv/> (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrs.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview.

Call (301) 443-6634 or send an email to ahertzog@hrs.gov if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the June meeting will include, but are not limited to: updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (<http://www.hrsa.gov/vaccinecompensation/accv.htm>) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857 or email: ahertzog@hrs.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by email, mail, or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.