

(919) 490-1010, Email: cferrell@aamro.com, Web site: <http://www.aamro.com/>;

Medical Review Officer Certification Council (MROCC), 836 Arlington Heights Road, #327, Elk Grove Village, IL 60007, Phone: (847) 631-0599, Fax: (847) 483-1282, Email: mrocc@mrocc.org, Web site: <http://www.mrocc.org/>.

(2) Additionally, the HHS Secretary lists the following entities that offer MRO training as a prerequisite for MRO certification by the above-listed approved entities:

American College of Occupational and Environmental Medicine (ACOEM), 25 Northwest Point Boulevard, Suite 700, Elk Grove Village, IL 60007-1030, Phone: (847) 818-1800, Fax: (847) 818-9266, Contact Form: <http://www.acoem.org/contactacoem.aspx>, Web site: <http://www.acoem.org/>;

American Society of Addiction Medicine (ASAM), 4601 N. Park Avenue, Upper Arcade #101, Chevy Chase, MD 20815, Phone: (301) 656-3920, Fax: (301) 656-3815, Email: email@asam.org, Web site: <http://www.asam.org/>.

DATES: HHS approval is effective January 14, 2013.

FOR FURTHER INFORMATION CONTACT:

Jennifer Fan, Pharm.D., J.D., Division of Workplace Programs (DWP), Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), 1 Choke Cherry Road, Room 7-1038, Rockville, MD 20857; Telephone: (240) 276-1759; Email: jennifer.fan@samhsa.hhs.gov.

Dated: January 4, 2013.

Kathleen Sebelius,
Secretary.

[FR Doc. 2013-00476 Filed 1-11-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0045]

Draft Guidance for Industry on Abuse-Deterrent Opioids—Evaluation and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Abuse-Deterrent

Opioids—Evaluation and Labeling.” The draft guidance describes how abuse-deterrent properties of opioid analgesic products should be studied and evaluated, and what claims regarding such properties may be suitable for inclusion in labeling. In addition to general input on this draft guidance, FDA is seeking input on the research topics outlined in the final section of the draft guidance. FDA also intends to hold a public meeting to solicit additional input from affected stakeholders on the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 15, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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.

FOR FURTHER INFORMATION CONTACT: Matthew Sullivan, Center for Drug Evaluation and Research (HFD-170), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3160, Silver Spring, MD 20993, 301-796-1245, matthew.sullivan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Abuse-Deterrent Opioids—Evaluation and Labeling.” Prescription opioid analgesics are an important component of modern pain management, but abuse and misuse of these products remains a serious and growing public health problem. One important effort in reducing abuse and misuse is the development of opioid analgesics specially formulated to deter abuse. FDA considers development of abuse-deterrent opioid analgesics to be a

public health priority and is encouraging their development.

This draft guidance is intended to provide industry with a framework for evaluating and labeling abuse-deterrent opioid products. The draft guidance discusses how the potentially abuse-deterrent properties of an opioid analgesic formulated to deter abuse should be studied, specifically addressing in vitro studies, pharmacokinetic studies, human abuse potential studies, and postmarket studies. The draft guidance also describes the types of information and claims that may be suitable for inclusion in labeling.

Providing a clear framework for the evaluation and labeling of the abuse-deterrent properties of opioid analgesics intended to deter abuse should help to incentivize the development of safer, less abusable opioid analgesics, and should also facilitate the dissemination of fair and accurate information regarding such products. FDA also expects that the publication of this draft guidance will stimulate a productive discussion among FDA, industry, and other stakeholders concerning the appropriate development, evaluation, and labeling of these products. In the final section of the draft guidance, FDA also lists several areas where additional scientific research and analysis would be especially helpful.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). FDA also intends to hold a public meeting to solicit additional input from affected stakeholders on the draft guidance. The guidance, when finalized, will represent the Agency’s current thinking on evaluation and labeling of abuse-deterrent opioids. 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 statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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>.

III. 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: January 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-00474 Filed 1-11-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Blood 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: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on February 12, 2013, from 8:30 a.m. to 5 p.m.

Location: 5630 Fishers Lane, FDA Conference Room 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be webcast. The webcast will be available at the following link: <http://fda.yorkcast.com/webcast/Viewer/?peid=9e38bbbbc4ae4327ab895d98a845fdd11d>.

Contact Person: Bryan Emery or Pearline Muckelvene, Center for Biologics Evaluation and Research, HFM-71, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1277 or 301-827-1281, 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 February 12, 2013, the Committee will meet in open session to discuss Cangene's biologics license application for Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)- (Equine) seeking licensure under FDA's authority to approve a product based on evidence of safety in humans and effectiveness from studies in animals when human efficacy studies are not ethical or feasible.

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 February 5, 2013. On February 12, 2013, oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 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 January 28, 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 January 29, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. Seating for this meeting may be limited, so the public is encouraged to watch the free webcast if you are unable to attend. The

link for the webcast will be available at 8 a.m. the morning of February 12, 2013.

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 Bryan Emery 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: January 8, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-00491 Filed 1-11-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the 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 Committees: Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 5, 2013, from 8 a.m. to 4 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