4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

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

Medical Gas Regulation Review; Announcement of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting on whether any changes to Federal drug regulations are necessary for medical gases. The topic to be discussed is whether any changes to the Federal drug regulations are necessary for medical gases as part of the implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Date and Time: The meeting will be held on December 6, 2013, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early.

Location: The meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating (please note that all visitors to the White Oak Campus must enter through Building 1). The meeting is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

Contact Persons: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-3519, FAX: 301-847-8753, email: Mary.Gross@fda.hhs.gov; or Christine Kirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-2465, FAX: 301-847-8440, email: Christine.Kirk@fda.hhs.gov; or Urvi Desai, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, email: Urvi.Desai@fda.hhs.gov.

Registration and Requests for Oral Presentations: If you wish to a make an oral presentation, you must register by submitting your name, title, firm name, address, telephone, email address, and FAX number, to Mary Gross (see Contact Persons) by December 2, 2013. Please also provide the type of organization you represent (e.g., industry, consumer organization), and a brief summary of your remarks (including the discussion topic(s) that will be addressed).

FDA will try to accommodate all persons who wish to make a presentation; however, the duration of each speaker's presentation may be limited by time constraints. FDA will notify registered presenters of their scheduled presentation times. Persons registered to speak should check in before the meeting and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. An agenda of the meeting will be made available at least 3 days before the meeting at http://www.fda.gov/Drugs/NewEvents/ucm370351.htm.

This public meeting will be Webcast and the URL will be posted at http://www.fda.gov/Drugs/NewEvents/ucm370351.htm at least 1 day before the meeting. A video record of the public meeting will be available at the same Web site address for 1 year. If

you need special accommodations because of disability, please contact Mary Gross (see Contact Persons) at least 7 days in advance.

Comments: Regardless of attendance at the public meeting, interested persons may submit electronic comments to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with Docket No. FDA-2013-N-0260, which has previously been established to accept comments regarding this issue. In order to receive consideration in advance of the delivery of the report (discussed further in this document), comments must be received by December 16, 2013. 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.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed FDASIA (Public Law 112-144) into law. Section 1112(a) of FDASIA provides that not later than 18 months after its enactment, the Secretary, after obtaining input from medical gas manufacturers and any other interested

members of the public, shall determine whether any changes to the Federal drug regulations are necessary for medical gases and submit a report regarding any such changes to the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives. Section 1112(c)(1) defines "Federal drug regulations" to mean "regulations in title 21 of the Code of Federal Regulations pertaining to drugs." Section 1112(b) provides that if the Secretary determines that changes to the Federal drug regulations are necessary for medical gases, the Secretary shall issue final regulations revising the Federal drug regulations with respect to medical gases not later than 48 months after the enactment of FDASIA.

On March 22, 2013, FDA issued a Federal Register notice (78 FR 17611), which established a public docket (Docket No. FDA-2013-N-0260) to request comments from medical gas manufacturers and any other interested members of the public on whether any changes to Federal drug regulations are necessary for medical gases.

II. Purpose and Scope of the Meeting

We are holding this meeting to provide an additional opportunity for medical gas manufacturers and any other interested members of the public to provide input on whether any changes to Federal drug regulations are needed for medical gases.

Dated: October 28, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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