4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1090]

Provisions of the Food and Drug Administration Safety and Innovation Act Related to Medical Gases; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket for information pertaining to FDA's implementation of the provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA) related to medical gases. This action is intended to ensure that information submitted to FDA on the implementation of the medical gas provisions of FDASIA is available to all interested persons in a timely fashion.

DATES: Submit electronic or written comments by [INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed into law FDASIA (Public Law 112-144, 126 Stat. 993). Title XI, Subtitle B, section 1111 of FDASIA added new sections 575, 576, and 577 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding medical gases. Among other things, these new sections define the terms "designated medical gas" and "medical gas" and establish the process for the certification of a medical gas as a designated medical gas. (See sections 575(1) and (2) of the FD&C Act.) The sections describe the process for filing a request for certification and describe the information that should be included in the request for certification. (See section 576(a) of the FD&C Act.) Under section 576(a)(3) of the FD&C Act,

if a certification is granted for a designated medical gas, the designated medical gas will be deemed to have in effect an approved new human drug application under section 505 (21 U.S.C. 355) or an approved new animal drug application under section 512 (21 U.S.C. 360b) of the FD&C Act for certain specified indications and subject to all applicable postapproval requirements. Under section 576(a)(1) of the FD&C Act, requests for certification may be submitted to FDA beginning 180 days after the enactment of FDASIA, or January 5, 2013.

FDA is establishing a public docket for information pertaining to FDA's implementation of these new medical gas provisions. This action is intended to ensure that information submitted to FDA on the implementation of the medical gas provisions of FDASIA is available to all interested persons in a timely fashion. The Compressed Gas Association and the Gases and Welding Distributors Association voluntarily submitted to the Agency its views on implementation of the medical gas provisions of FDASIA. FDA plans to place these comments in the public docket so they are readily available to all interested members of the public. FDA expects to place all additional submissions containing recommendations on how the Agency should implement the medical gas provisions of FDASIA in this docket, and directs the public to submit all comments related to these provisions to this docket. This docket will be open for comments for 1 year from the date of publication of this notice. In addition, as FDA implements the medical gas provisions of FDASIA, FDA plans to open other dockets. For example, we plan to issue a separate Federal Register notice in the future to provide the public with an opportunity to submit comments on section 1112 of FDASIA. Section 1112(a)(1) of FDASIA provides that not later than 18 months after the date of the enactment of FDASIA, the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public,

must determine whether any changes to the Federal drug regulations are necessary for medical gases.

II. Comments

Interested persons may submit either written comments 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: November 19, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-28431 Filed 11/21/2012 at 8:45 am; Publication Date: 11/23/2012]