4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part Chapter 1

[Docket No. FDA-2013-N-0260]

Provisions of the Food and Drug Administration Safety and Innovation Act Related to Medical Gases; Request for Comments Regarding Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is inviting comments from the public on whether any potential changes to the Federal drug regulations are necessary for medical gases.

DATES: Submit electronic or written comments by [INSERT DATE 60 DAYS 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 the Food and Drug Safety and Innovation Act (FDASIA) (Public Law 112-144) into law. Section 1112(a) of FDASIA provides that not later than 18 months after its enactment, the Secretary of Health and Human Services, 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)(l) 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. FDA is opening this docket to provide the public with an opportunity to submit comments on whether any potential changes to Federal drug regulations are necessary for medical gases.

II. Opportunities for Comment on Other Medical Gas Dockets

FDASIA also added new sections regarding medical gases to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (see Title XI, Subtitle B, section 1111 of FDASIA, adding new sections 575, 576, and 577 to the FD&C Act). FDA has previously issued two other Federal Register notices related to these new sections.

On November 23, 2012 (77 FR 70166), FDA issued a Federal Register notice establishing a public docket (Docket No. FDA-2012-N-1090) for information pertaining to FDA's implementation of the provisions of FDASIA related to medical gases. Interested persons may submit comments relevant to that Federal Register notice (see ADDRESSES) under Docket No. FDA-2012-N-1090.

On December 18, 2012 (77 FR 74852), FDA issued a notice of availability announcing publication of a draft guidance for industry entitled "Certification Process for Designated Medical Gases" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332136.pdf) (Docket No. FDA-2012-D-1197). The draft guidance describes the new certification process created by FDASIA for certain medical gases and explains how FDA plans to implement that process. Interested persons may submit comments regarding the draft

guidance (see ADDRESSES) under Docket No. FDA-2012-D-1197. Please note that although comments on draft guidance may be submitted at any time, FDA requested that comments be submitted by February 19, 2013, in order to allow adequate time for the comments to be considered while the Agency is preparing final guidance.

III. 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.

Dated: March 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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