4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2013-N-0365]

Establishment of a Public Docket for Administrative Detention Under the Food and Drug Administration Safety and Innovation Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments pertaining to the implementation of its administrative detention authority with respect to drugs under the Food and Drug Administration Safety and Innovation Act (FDASIA). This document is intended to solicit input from all relevant stakeholders before FDA issues regulations to implement its administrative detention authority with respect to drugs and to announce that such information submitted to FDA is available to all interested persons in a timely fashion.

DATES: Submit electronic or written comments by [INSERT DATE 30 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:

Charlotte Hinkle,

Office of Regulatory Affairs,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 32, rm. 4345,

Silver Spring, MD 20993-0002,

301-796-5300,

FDASIAImplementationORA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed FDASIA (Public Law 112-144) into law. Section 709 of FDASIA amends section 304(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334(g)) to provide FDA administrative detention authority with respect to drugs. Section 304(g) of the FD&C Act, as amended by FDASIA, provides FDA the same authority to detain drugs that section 304(g) had already provided FDA with respect to devices and tobacco products.

Section 709 of FDASIA requires the Secretary to "consult with stakeholders, including manufacturers of drugs" before issuing implementing regulations. Section 709 also provides that FDA must issue a final rule to implement its administrative detention authority with respect to drugs before the amendments to section 304(g) of the FD&C Act take effect.

FDA is opening a docket for 30 days to solicit input from all relevant stakeholders regarding FDA's issuance of a regulation for the administrative detention of drugs. This docket is intended to ensure that stakeholders have an opportunity to provide comments before FDA

issues regulations on administrative detention with respect to drugs and that such information submitted to FDA is available to all interested persons in a timely fashion.

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 will be posted to the docket at http://www.regulations.gov and may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-08120 Filed 04/08/2013 at 8:45 am; Publication Date: 04/09/2013]