4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0710]

# Guidance for Industry on Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." The Food and Drug Administration Safety and Innovation Act (FDASIA) added a provision to the Food, Drug, and Cosmetic Act (the FD&C Act) concerning inspections that makes a drug adulterated. This guidance defines the types of actions, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of making a drug adulterated.

DATES: Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., rm. 4138, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the 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: Emily M. Leongini, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 10902 New Hampshire Ave., Bldg., 32, rm. 4339, Silver Spring, MD 20903, 301-796-5300.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." On July 9, 2012, FDASIA (Public Law 112-144) was signed into law. Section 707 of FDASIA adds 501(j) to the FD&C Act to make a drug adulterated that "has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection." As required by Section 707, FDA is issuing this guidance to define the types of action, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of Section 501(j) of the FD&C Act.

In July 2013, FDA issued a draft guidance for industry of the same title (78 FR 42387, July 15, 2013). In response to docket comments, we revised the guidance to clarify FDA's expectations regarding the types of action, inaction, and circumstances that make a drug adulterated under 501(j) of the FD&C Act. Among other things, we added examples that may

constitute reasonable explanations for actions, inactions, or circumstances that could otherwise be considered delaying, denying, or limiting inspection, or refusing to permit entry or inspection.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." 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/RegulatoryInformation/Guidances/ucm122044.htm or http://www.regulations.gov.

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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