4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0690]

Product Shortage Report; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a medical product shortage report entitled "A Review of FDA's Approach to Medical Product Shortages." The Agency is making the report available by placing it in the docket opened for a previous public workshop on drug shortages. The report discusses the Agency's approach to product shortages, particularly those products regulated by the FDA Center for Drug Evaluation and Research (CDER). FDA requests comments, until December 23, 2011, on the report and its recommendations, including whether there are additional suggestions for recommendations and how we should prioritize work on these recommendations.

DATES: Submit either electronic or written comments by December 23, 2011.

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.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 29, 2011 (76 FR 60505), FDA opened a comment period for a public workshop notice which published in the Federal Register of July 28, 2011 (76 FR 45268). This document announces the availability of a product shortage report by placing it in the docket of the public workshop on drug shortages. This report provides background information on product shortages, discusses four FDA product centers' various approaches to addressing product shortages, particularly those in CDER, and includes recommendations for FDA and others. FDA is requesting comment on the report and its recommendations, including whether there are additional suggestions for recommendations and how we should prioritize work on these recommendations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm or http://www.regulations.gov.

Dated: October 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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