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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0675]

Draft Guidance for Industry on Good Importer Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing on behalf of several members of the Interagency Working Group on Import Safety (agencies) the availability of a draft guidance for industry entitled “Good Importer Practices.” This draft guidance document provides general recommendations to importers on possible practices and procedures they may follow to increase the likelihood the products they import are in compliance with applicable U.S. safety and security requirements. The recommendations provided here are intended to promote and facilitate an assessment by importers of a product’s life cycle so the importer may make sound decisions about how best to address the product’s potential to cause harm and to facilitate compliance with U.S. requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agencies consider your comments on this draft guidance before they begin work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Food and Drug Administration, Office of Policy and Planning, 10903 New

Hampshire Ave., White Oak Building 1, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Shuren, Food and Drug Administration, 10903 New Hampshire Avenue, White Oak Building 1, Silver Spring, MD 20993, 301-796-4840.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing on behalf of the agencies¹ the availability of a draft guidance for industry entitled “Good Importer Practices.” This draft guidance is issued in response to recommendations contained in the *Action Plan for Import Safety: A Roadmap for Continual Improvement* (Action Plan) issued on November 6, 2007, by the Interagency Working Group on Import Safety (Working Group) established by Executive Order 13439 (see <http://www.importsafety.gov/report/actionplan.pdf>). The Action Plan recommends that the Federal Government work with the importing community and other members of the public to develop Good Importer Practices and issue guidance.

¹ The agencies who developed this draft guidance are the U.S. Consumer Product Safety Commission, the Department of Agriculture, the Department of Commerce, the Department of Health and Human Services (FDA), the Department of Homeland Security, the Department of Transportation, and the Environmental Protection Agency, as well as with input from the Office of the U.S. Trade Representative.

The Action Plan specifies that the focus of these practices should be to ensure that imported products meet U.S. standards, as well as to promote effective supply-chain management. The Action Plan recommended that these practices be risk-based and provide concrete guidance to the importing community for evaluating imported products. This evaluation would be based on due diligence and preventive control principles.

This guidance is intended for use by the importer that initiates or causes the entry or attempted entry of foreign-sourced products into the United States or the reimportation of U.S.-made products (American goods returned) for commercial purposes to help ensure that such products are safe and comply with applicable U.S. requirements.² At any point during the product's life cycle, hazards can be introduced that may place consumers at risk unless appropriate preventive controls are implemented. In general, the recommendations advise the importer to know the foreign firms with whom they do business and through which the products they purchase pass, understand the products they import and their vulnerabilities, understand the hazards that may be introduced during the product life cycle, and ensure that these hazards have been properly controlled and monitored. Importers should consider instituting practices to identify and minimize risk. Importers should put into place controls for known vulnerabilities, such as to microbiological contamination or product defects, and monitor for other risks, such as counterfeiting or intentional contamination.

These Good Importer Practices are broadly organized by four guiding principles. These four guiding principles are as follows:

² While this guidance document sets out principles and recommendations for helping to ensure the safety and security of imported products, the principles and the non-customs related recommendations are also applicable to helping ensure the safety and security of products that are domestically produced.

- Establishing a product safety management program
- Knowing the product and applicable U.S. requirements
- Verifying product and firm compliance with U.S. requirements throughout the supply chain and product life cycle
- Taking corrective and preventive action when the imported product or firm is not compliant with U.S. Requirements

The guidance suggests actions the importer can take to accomplish each of these objectives.

This draft guidance is being issued consistent with the Office of Management and Budget's Final Bulletin for Agency Good Guidance Practices (No. 07-02 (M-07-07)). The draft guidance, when finalized, will represent the agencies' current thinking on Good Importer Practices. It does not create or confer any rights for or on any person and does not operate to bind the agencies or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable U.S. statutes and regulations.

II. Comments

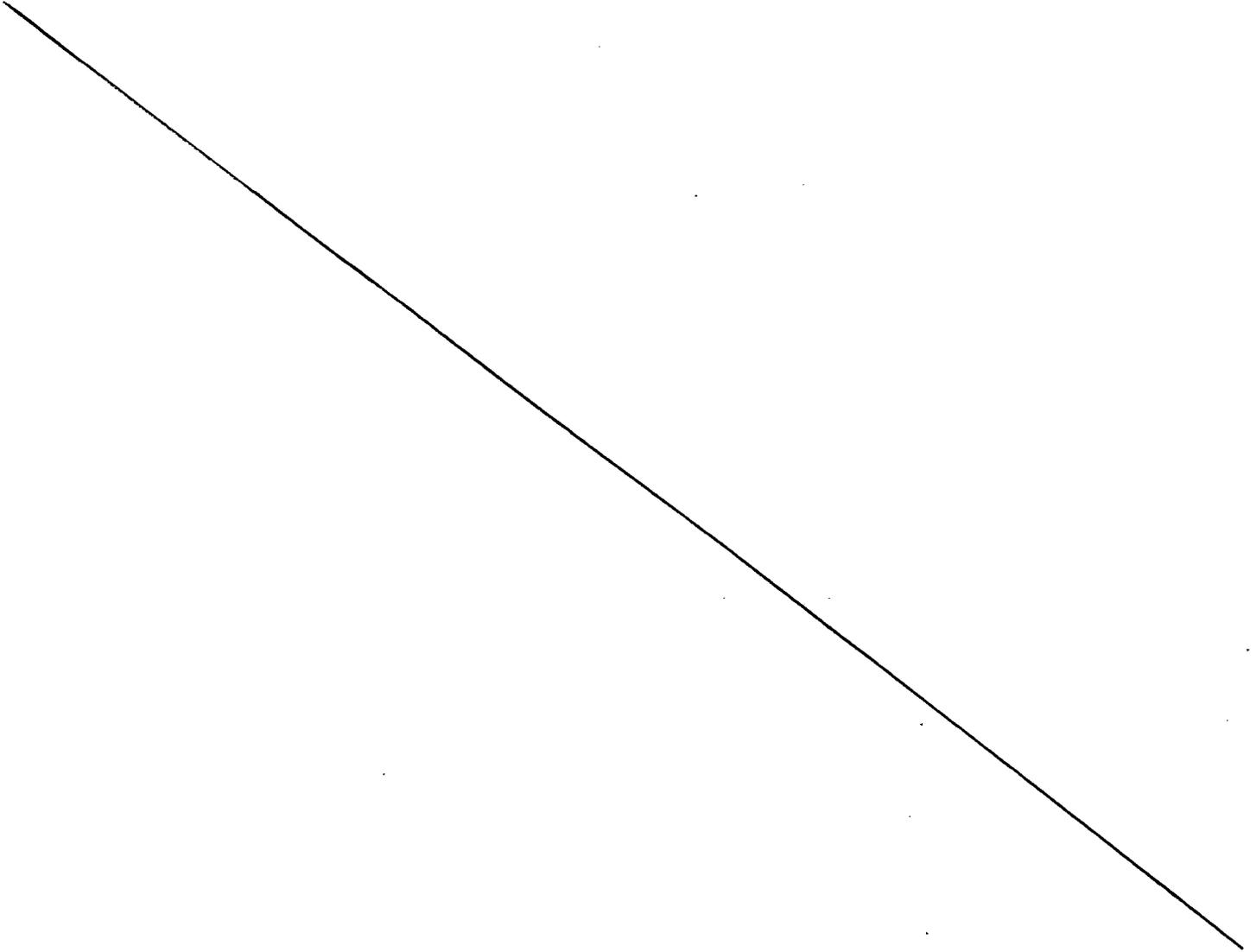
FDA is coordinating the receipt of submitted comments on behalf of the agencies. Interested persons may submit to FDA's Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system.

Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/oc/guidance/goodimportpractice.html> or <http://www.regulations.gov>.



Dated: January 8, 2009
January 8, 2009.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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