

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0510]

Draft Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories. The draft guidance document provides information and recommendations about accreditation standards for laboratories and the quality and type of data that accredited laboratories produce to support testing results submitted to FDA about the admissibility of detained articles offered for import. We are taking this action under a recommendation made by the President's Interagency Working Group on Import Safety (Working Group).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Executive Operations (HFC-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Donna Porter, Division of Field Science (HFA-141), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7605.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories." The draft guidance is about accreditation standards for laboratories and about the quality and type of data that accredited laboratories should produce in support of testing results submitted to FDA pertaining to the admissibility of detained articles offered for import of all product types (i.e., biological products, drugs, devices, and food) that we regulate. FDA is taking this action under a recommendation made by the President's Interagency Working Group on Import Safety (Working Group). The Working Group was to conduct a comprehensive review of the U.S. import system and identify ways to further increase the safety of imports entering the country, and it presented its initial findings to the President on September 10, 2007, in a report entitled "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety." On November 6, 2007, the Working Group presented to the President its Import Safety Action Plan (Action Plan), which contains short- and long-term recommendations for continuing to improve the safety of imports entering the United States. The Action Plan recommended that FDA issue guidance that "would set standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved." The issuance of the draft guidance is, therefore, consistent with the Action Plan and also consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding the draft guidance. 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. A copy of the draft guidance and received comments are available for public examination 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 draft guidance at either <http://www.fda.gov/ora> or <http://www.regulations.gov>