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Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501-3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control No. 0910-0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910-0485.

#### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written 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.

Dated: October 17, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0476]

#### Guidance for Industry on Product Recalls, Including Removals and Corrections; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry entitled "Product Recalls, Including Removals and Corrections." This document provides members of industry regulated by FDA with guidance for handling all aspects of product recalls, including removals and corrections. The guidance applies to the recalls of all FDA-regulated products. **DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of "Product Recalls, Including Removals and Corrections" to the Food and Drug Administration, Office of Enforcement, Division of Compliance Management and Operations (HFC-210), 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. For documents without a docket number, include the title of the guidance document. Send one self-addressed adhesive label to assist that office in processing your requests. You may fax your request to 301-827-0342. Submit written comments on the 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.fda.gov/dockets/ecomments>. Comments may be submitted at any time. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. **FOR FURTHER INFORMATION CONTACT:** Willie R. Bryant, Jr., Senior Recall

Officer, Division of Compliance Management and Operations (HFC-210), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-0391.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance document that provides the agency's recommendations to members of FDA-regulated industry for the handling of product recalls. This document sets forth the agency's existing practices in recommending procedures for addressing all aspects of product recalls, including removals and corrections. The cooperation of manufacturers and distributors in expediting recall activities is vital. The recalling firm's notification of the local FDA District Recall Coordinator and submission of recall information outlined in the guidance allows FDA the opportunity to review, comment, offer assistance, and monitor the recall process.

##### II. Significance of Guidance

This is a level 2 guidance issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The agency is implementing this guidance document immediately in accordance with § 10.115(g)(4)(i)(B) and inviting public comment in accordance with § 10.115(g)(4)(i)(C). This guidance represents the agency's current thinking on product recalls, including removals and corrections. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### III. Electronic Access

Persons interested in obtaining an electronic copy of the guidance may do so using the Internet. ORA maintains an entry on the Internet for easy access to information, including recent publications, consumer information references, compliance and inspection references, and recall information (model recall letters and press releases) that may be downloaded to a personal computer with Internet access. The ORA home page may be accessed at <http://www.fda.gov/ora/>. A search capability for all ORA guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.