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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-1109]

### Mercury Compounds in Drugs and Food; List and Analysis; Availability

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Mercury Compounds in Drugs and Food." The document discusses drugs (including biologics) and foods that contain intentionally introduced mercury compounds. In addition, for those products that contain intentionally introduced mercury compounds, the document provides a quantitative and qualitative analysis of the mercury compounds in the products. This document has been prepared in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA), section 413, entitled "Food and Drug Administration Study of Mercury Compounds in Drugs and Food."

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the document entitled "Mercury Compounds in Drugs and Food" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Copies of the document are available on the Internet at <http://www.fda.gov/cder/index.htm>. Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

For human drug products: Gerald M. Rachanow, Center for Drug Evaluation and Research

(HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

For human biological products: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

For veterinary drug products: William C. Keller, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6641.

For food and dietary supplement products: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5343.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled “Mercury Compounds in Drugs and Food.” This document discusses drugs (including biologics) and foods that contain intentionally introduced mercury compounds. In addition, for those products that contain intentionally introduced mercury compounds, the document provides a quantitative and qualitative analysis of the mercury compounds’ in the products.

This document is part of FDA’s implementation of FDAMA (Public Law 105-115), enacted on November 21, 1997. Section 413 of FDAMA required FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. FDAMA required the agency to compile the list and provide the analysis within 2 years after the date of its enactment.

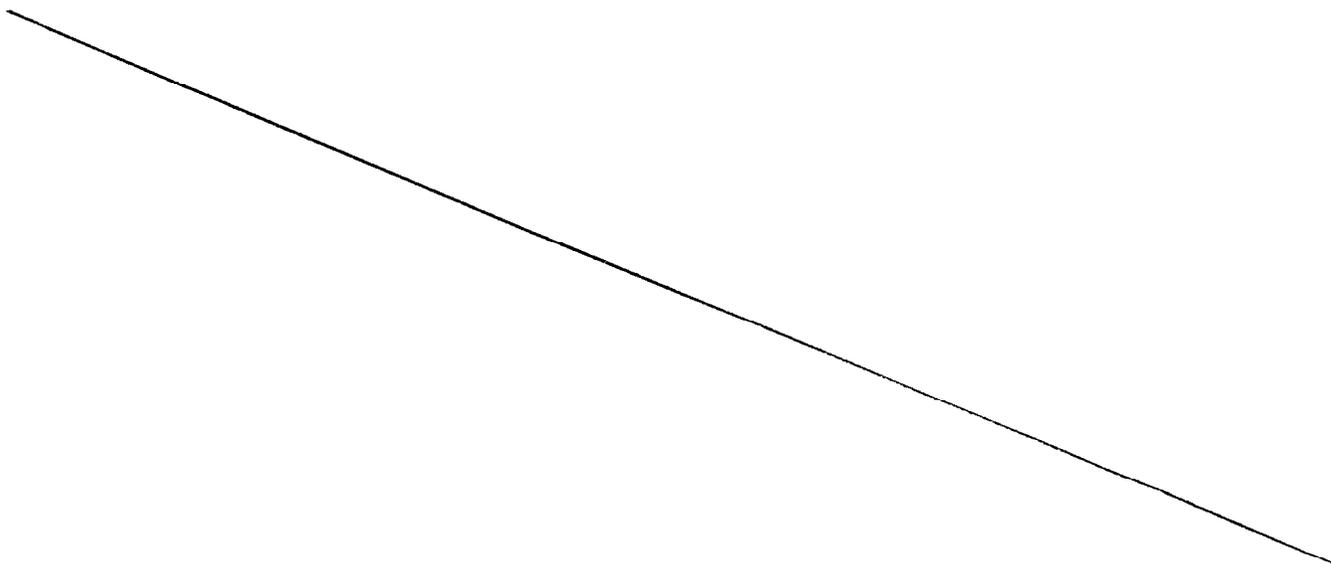
The statute did not differentiate whether the mercury compound was present in a product as an active or inactive ingredient, whether the product was for human or veterinary use, or whether the product was sold by prescription or over-the-counter. Food products include dietary supplements.

In the **Federal Register** of December 14, 1998 (63 FR 68775) and April 29, 1999 (64 FR 23083), FDA published notices requesting data and information on any intentionally introduced mercury compounds in these types of products. The agency asked manufacturers of affected products to provide: (1) The commercial name of the product that contains the mercury compound; (2) the chemical name, quantitative amount, and purpose of the mercury compound present; (3) a copy of the product's labeling; and (4) an estimate of the amount of the mercury compound used annually in manufacturing the product.

The agency received 41 responses to the two request-for-data notices. The agency also reviewed information contained in its Drug Registration and Listing System and other sources to identify additional products that contain intentionally introduced mercury compounds. The document discusses the information that the agency reviewed and provides a list and analysis of the products that were identified. The document is intended to provide information and does not set forth any requirements.

## **II. Comments**

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and



received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m.,  
Monday through Friday.

Dated: 11/15/99  
November 15, 1999

  
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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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