

request for information to update a list of drug and biologic products that contain intentionally introduced mercury compounds, e.g., phenylmercuric acetate, phenylmercuric nitrate, and thimerosal. This request is part of the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written and electronic comments and information by April 4, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Public Law 105-115) was enacted on November 21, 1997. Section 413 of FDAMA entitled "Food and Drug Administration Study of Mercury Compounds in Drugs and Food" 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. The statute did not differentiate whether the mercury compound was present in the products as an active or an inactive ingredient and required FDA to compile the list and provide the analysis within 2 years after the date of its enactment. FDA prepared this list and announced its availability in the **Federal Register** of November 19, 1999 (64 FR 63323).

II. Request for Information

The agency is aware that some manufacturers or distributors with products on the list have reformulated their products since 1999. Accordingly, the agency would like to update the list to delete any products that no longer contain mercury ingredients. The agency is requesting any affected manufacturer or distributor with a product(s) on the list that no longer contains mercury to send an acknowledgement to the agency [to Docket No. 98N-1109] stating that the product(s) has been reformulated to no longer contain mercury. The agency will compile this information and announce the availability of an updated list in a future issue of the **Federal Register**.

The agency wishes to assure that it has a copy of the revised labeling for any product that has been reformulated. Part 207 (21 CFR part 207) entitled "Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution" provides that owners or operators of drug establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs register and submit a list of every drug in commercial distribution (§ 207.20(a)). Owners or operators of establishments that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may submit listing information directly to FDA and obtain a labeler code (§ 207.20(b)). Registrants are required to provide a copy of all current labeling for each new drug (§ 207.25(b)(2)) and human prescription drug that is not a new drug (§ 207.25(b)(4)), and a copy of the label for each human over-the-counter drug listed that is not a new drug (§ 207.25(b)(5)). Information about inactive ingredients in the product is requested but not required (§ 207.31(b)).

Owners and operators of all registered establishments are required to update their drug listing information every June and December (§ 207.21(b)). The updated information includes listing each drug for which commercial distribution has been discontinued or for which any material change has occurred in any information previously submitted (e.g., reformulation) (§ 207.30(a)(2) and (a)(4), respectively). The agency is requesting that any manufacturers or distributors who have reformulated their products to remove the mercury ingredients update their labeling in accordance with part 207. These submissions should be highlighted with the words "Mercury List" on the envelope. The submission of information to FDA under part 207 is an approved collection of information under the Office of Management and Budget (OMB) control number 0910-0045 entitled "Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution," which expires July 31, 2004.

Affected manufacturers or distributors should submit the acknowledgement information to the Dockets Management Branch (see **ADDRESSES**). Two copies of all written information are to be submitted. Anyone submitting information electronically may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the list and received comments may be seen in the Dockets Management Branch between 9

a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

The list is entitled "Mercury in Drug and Biologic Products" and is available on the Internet at <http://www.fda.gov/cder/fdama/mercury300.htm>.

Dated: January 15, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0834]

Draft Guidance for Industry on Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling." The draft guidance is intended to assist applicants in developing labeling for new drug applications for such drug products. This is the second draft of the guidance, which initially issued in September 1999.

DATES: Submit written or electronic comments on the draft guidance by April 4, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), 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. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.