review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231). 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 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.

Dated: July 16, 2003.

**Linda S. Kahan,**

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

[FR Doc. 03–19622 Filed 7–31–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1998N–1109]**

## Mercury Compounds in Drugs and Food; List

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is updating a list of drug and biologic products that contain intentionally introduced mercury compounds, e.g., phenylmercuric acetate, phenylmercuric nitrate, thimerosal. This list is part of the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the document entitled ''Mercury in Drug and Biologic Products; 2003 Update'' 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/fdama/mercury300.htm*. Submit written comments on the document 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*.

**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). 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*.

Five manufacturers and distributors subsequently informed FDA that 10 products had been reformulated to delete the mercury ingredients or were no longer being marketed. However, FDA did not update the list at that time.

### II. Updating the List

In the **Federal Register** of February 3, 2003 (68 FR 5299), FDA published a notice requesting information to update this list. FDA was aware that other manufacturers or distributors with products on the list had reformulated their products since 1999. FDA requested any affected manufacturer or distributor to inform us which product(s) on the list had been reformulated and no longer contain mercury ingredients. Eleven manufacturers provided information, which resulted in 39 additional products being deleted from the list and one product being added to the list. The new list now includes 171 products. The list continues to provide information and does not set forth any requirements.

### III. 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 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 list and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–19620 Filed 7–31–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

## Proposed Collection; Comment Request; Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture. *Type of Information Collection Request:* Extension of a currently approved collection (0925–0406, expiration 11/31/03). *Need and Use of Information Collection:* The Agricultural Health Study is in its fifth year of follow-up data collection for a prospective cohort of 89,658 farmers, their spouses, and commercial applicators of pesticides from Iowa and North Carolina. Follow-up is not yet