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

complete for a segment of the cohort, commercial applicators (n=4,916). An extension until November 30, 2005 is requested to complete this data collection. *Frequency of Response:* Single time reporting. *Affected Public:* Individuals. *Type of Respondent:* Commercial pesticide applicators. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,458; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 1.66; and *Estimated Total Annual Burden Hours Requested:* 2,940. The annualized cost to respondents is estimated at: $29,400. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael C.R. Alavanja, Dr. P.H., Epidemiology and Biostatistics Program, Division of Cancer Etiology, National Cancer Institute, EPN 8000, 6120 Executive Boulevard, Rockville, MD 20852; or call (310) 435–4720; or e-mail your request, including your address to: *alavanjam@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before September 29, 2003.

Dated: July 24, 2003.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 03–19558 Filed 7–31–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Lung Tissue Research Consortium.

Date: August 13, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Arthur N. Freed, Phd., Review Branch, Room 7186, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892, (301) 435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–19562 Filed 7–31–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The Meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, International Patient Registry and Repository for Temporomandibular.

Date: October 17, 2003.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Patricia A Haggerty, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7188, MSC 7924, Bethesda, MD 20892, 301/435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–19564 Filed 7–31–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging, Special Emphasis Panel, Aging Disease Studies.