| Committee Name | Tentative Date(s) of Meetings | Advisory Committee 10–Digit Information Line Code |
|---|---|---|
| Medical Devices Dispute Resolution Panel | Meeting(s) scheduled as needed | 3014510232 |
| Microbiology Devices Panel | March 31–April 1, June 16–17, September 19–20, December 8–9 | 3014512517 |
| Molecular and Clinical Genetics Panel | April 18–19, October 17–18 | 3014510231 |
| Neurological Devices Panel | April 28–29, June 20–21, September 22–23, December 1–2 | 3014512513 |
| Obstetrics and Gynecology Devices Panel | March 10–11, May 16–17, August 15–16, November 14–15 | 3014512524 |
| Ophthalmic Devices Panel | March 17–18, May 12–13, July 28–29, September 29–30, November 17–18 | 3014512396 |
| Orthopaedic and Rehabilitation Devices Panel | January 31–February 1, April 7–8, July 25–26, November 3– 4 | 3014512521 |
| Radiological Devices Panel | February 1, May 10, August 2, November 1 | 3014512526 |
| National Mammography Quality Assurance Advisory Committee | April 18 | 3014512397 |
| Technical Electronic Product Radiation Safety Standards Committee | May 18 | 3014512399 |
| CENTER FOR FOOD SAFETY AND APPLIED NUTRITION | | |
| Food Advisory Committee—Parent | July-day to be announced | 3014510564 |
| Additives and Ingredients Subcommittee | June-day to be announced | Do. |
| Biotechnology Subcommittee | July-day to be announced | Do. |
| Contaminants and Natural Toxicants Subcommittee | November-day to be announced | Do. |
| Dietary Supplements Subcommittee | To be announced | Do. |
| Infant Formula Subcommittee | August-day to be announced | Do. |
| Nutrition Subcommittee | To be announced | Do. |
| CENTER FOR VETERINARY MEDICINE | | |
| Veterinary Medicine Advisory Committee | January 31, May 19, October 20 | 3014512548 |
| NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR) | | |
| Science Advisory Board to NCTR | March 30–31 | 3014512559 |
| Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants | May, September, November-days to be announced | 3014512560 |

Dated: December 8, 2004.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

[FR Doc. 04–27737 Filed 12–17–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0524]**

### Draft Guidance for Industry on ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information; Availability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 ''ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.'' The draft guidance is intended to assist applicants with the submission of abbreviated new drug applications (ANDAs) when a drug substance exists in polymorphic forms.

**DATES:** Submit written or electronic comments on the draft guidance by March 21, 2005. 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 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Andre Raw, Center for Drug Evaluation and Research (HFD–620), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5758.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides: (1) A framework for making regulatory decisions on drug substance sameness in terms of polymorphic form, and (2) decision trees which provide a recommended course to monitor and control polymorphs in the drug substance and/or drug product when the drug substance exists in relevant polymorphic forms.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on pharmaceutical solid polymorphism. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 11, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–27736 Filed 12–17–04; 8:45 am]

**BILLING CODE 4160–01–S**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; The Framingham Study

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of the Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March June 30, 2004, page 39486, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* The Framingham Study. *Type of Information Collection Request:* Reinstatement of a currently approved collection (OMB No. 0925–0216). *Need and Use of Information Collection:* This study will conduct examinations and morbidity and mortality follow-up in original, offspring, and third-generation participants to study the determinants of cardiovascular disease. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households, businesses or other for profit, small businesses or organizations. *Type of Respondents:* Adult men and women; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number or Respondents:* 5,649; *Estimated Number of Responses Per Respondent:* 2.29; *Average Burden Hours Per Response:* 0.6; and *Estimated Total Annual Burden Hours Requested:* 6,886. There are no capital, operating or maintenance costs to report.

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---|---|---|---|---|
| Participants | 3,513 | 2.86 | 0.606 | 6,085 |
| Physician, hospital, nursing home staff | 1,068 | 1.0 | 0.67 | 716 |
| Participant's next of kin | 1,068 | 1.0 | .08 | 85 |
| Total | 6,649 | 2.29 | ..... | 6,886 |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address 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