

identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 11, 2002.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 02-29226 Filed 11-18-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0319]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by December 19, 2002.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607—(OMB Control Number 0910-0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business and all such establishments, and submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human and products. Section 607.20(a) requires certain establishments that engage in the manufacture of products to register and to submit a list of products in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of products to register within 5 days after beginning such operation and to submit a product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their product listing every June and December. Section 607.22 requires the use of Form FDA 2830 for registration and product listing. Section 607.25 indicates the information required for establishment registration and product listing. Section 607.26 requires certain changes to be submitted as an amendment to the establishment registration within 5 days of such changes. Section 607.30 requires establishments to update, as needed, their product listing information every June and at the annual registration. Section 607.31 requires that additional product listing information be provided upon FDA request. Section 607.40 requires foreign product establishments to register and submit the product listing information, the name and address of the establishment, and the name of the individual responsible for submitting product listing information. Among other uses, this information

assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's supply. Form FDA 2830, Establishment Registration and Product Listing, is used to collect this information. The likely respondents are banks, collection facilities, and component manufacturing facilities. FDA estimates the burden of this collection of information based upon the database and past experience of the Center for Biologics Evaluation and Research, Division of Applications in regulatory establishment registration and product listing. Most banks are familiar with the regulations and registration requirements to fill out this form.

In the **Federal Register** of August 2, 2002 (67 FR 50445), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received. The comment agrees that the information collection is necessary and the Form FDA 2830 is helpful with the registration process.

The comment stated that we underestimated the hours per response regarding the initial registration and product listing update. The comment stated that it might take up to 2 hours to complete the initial registration and 0.5 hours to complete the product listing update. We decline to change the estimates based on our review of the activities associated with completing the form. Although it may take some establishments longer to complete the form, others may complete the form more quickly. Since the reporting burden includes an estimated average of the time to complete the various activities associated with the form, we believe that the current burden estimates accurately reflect the range of time to complete the form.

The comment also requested that the annual registration process be automated so that each facility could electronically submit the form, if they desire to do so, and also requested that we continue to send a hard copy of the form and instructions as a reminder to registrants to re-register. We are currently in the process of setting up a program for electronic registration. Use of the electronic system will be voluntary. We intend to continue sending a hard copy of the form and instructions for the foreseeable future.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR                                                   | Form FDA 2830          | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------------------------------------------------|------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 607.20(a),<br>607.21, 607.22,<br>607.25, and 607.40      | Initial registration   | 300                | 1                             | 300                    | 1                  | 300         |
| 607.21, 607.22,<br>607.25, 607.26,<br>607.31, and 607.40 | Re-registration        | 2,867              | 1                             | 2,867                  | 0.5                | 1,434       |
| 607.21, 607.25,<br>607.30, 607.31,<br>and 607.40         | Product listing update | 75                 | 1                             | 75                     | 0.25               | 19          |
| Total                                                    |                        |                    |                               |                        |                    | 1,753       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 7, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–29295 Filed 11–18–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, National Cancer Institute.

*Date:* December 9, 2002.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To discuss the Stomach and Esophageal Cancers Progress Review Group Report.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Lisa Stevens, Executive Secretary, National Institutes of Health, Building 31, Room 3A30, Bethesda, MD 20892, 301/496–1458.

Information is also available on the Institute's/Center's home page; [deainfo.nci.nih.gov/advisory/joint/htm](http://deainfo.nci.nih.gov/advisory/joint/htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 6, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–29258 Filed 11–18–02; 8:45 am]

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## 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Review of K23 Grants.

*Date:* November 26, 2002.

*Time:* 1 pm to 3:30 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Robert B Moore, PhD, Review Branch, Room 7192, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892, 301–435–3541.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: November 13, 2002.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–29248 Filed 11–18–02; 8:45 am]

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## 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning