time to conduct studies and to prepare applications.

EFFECTIVE DATE: April 26, 2000.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1997 (62 FR 43535), FDA announced that orally administered drug products containing levothyroxine sodium are new drugs and required manufacturers to have approved applications as a condition of marketing. The notice advised that manufacturers who were marketing levothyroxine sodium drug products on or before August 14, 1997, may continue to market their products until August 14, 2000.[1] The notice stated that a manufacturer who marketed a levothyroxine sodium drug product without an approved application after that date would be subject to regulatory action.

FDA permitted this period of continued marketing because it regards levothyroxine sodium products as medically necessary and, therefore, wanted to allow sufficient time for manufacturers to conduct the required studies and to prepare and submit applications, as well as to allow the agency sufficient time to review these applications. FDA has now concluded that manufacturers may need additional time to conduct studies and to prepare applications. Therefore, the agency extends by 1 year the compliance date given in the **Federal Register** notice of August 14, 1997, to permit continued marketing of these products until August 14, 2001.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505 (21 U.S.C. 352, 355)) and under authority delegated to the Associate Commissioner for Regulatory Affairs (21 CFR 5.20).

Dated: April 18, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–10322 Filed 4–25–00; 8:45 am]

BILLING CODE 4160–01–F

[1] After August 14, 1997, a new levothyroxine drug product may not be introduced into the market unless FDA has approved an application for that product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 19, 2000, 10 a.m. to 2 p.m.

Location: Holiday Inn, Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville MD, 301–827–7001, email: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation of the data and rationale for the regulatory action regarding the withdrawal from the U.S. market of Rezulin™ (troglitazone, Parke-Davis Pharmaceutical Research, a Division of Warner-Lambert) for the treatment of type 2 diabetes mellitus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 15, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 15, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 17, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–10321 Filed 4–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB 0915–0174)—EXTENSION

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under Section 621 of Title VI and Section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the Section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to capital through the assumption of the mortgage credit risk by the Federal Government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are insured under these programs. The information is used to monitor the financial stability of the hospitals to protect the Federal investment in these facilities. The form used for the data collection is the Hospital Facility Data Abstract. No changes in the form are proposed.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Hospital Facility Data Abstract	150	1	1	150

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 19, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–10320 Filed 4–25–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; a Nested Case-Control Study of Lung Cancer and Diesel Exposure Among a Cohort of Non-Metal Miners

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:* A Nested Case-Control Study of Lung Cancer and Diesel Exhaust Among a Cohort of Non-Metal Miners. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This nested case-control study will examine lung cancer in non-metal miners and its association, if any, with diesel exhaust exposure. The study will involve approximately 160 deaths from lung cancer (the actual number will depend on the number of deaths occurring,but based on national rates we expect 160), and four controls matched to each death, identified from the cohort. Controls will be matched on mine, gender, race/ethnicity and year of birth (within 5 years). Detailed information regarding exposure to diesel exhaust will be obtained from employment records and measurements of diesel exhaust surrogates. Information on potential confounders will be obtained by interview and from environmental measurements. This information will be used in a study by the National Cancer Institute and the National Institute for Occupational Safety and Health to examine risk of mortality from lung cancer for various measures of diesel exhaust exposure, adjusted for smoking and other potential confounders. *Frequency of Response:* One-time study. *Affected Public:* Individuals. *Type of Respondents:* Workers or next of kin of workers. The annual reporting burden is as follows: *Estimated number of Respondents:* 227; *Estimated Number of Responses per Respondent:* One; *Average Burden Hours per Response:* 1.0; and *Estimated Total Annual Burden Hours Requested:* 227. There are no Capital Costs, Operating Costs, and/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) Whether the proposed collection or information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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 CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Debra Silverman, NCI Project Director, National Cancer Institute, Executive Plaza South, Room 8108, Rockville, Maryland 20892–7240, or call non-toll-free number (301) 435–4716, or FAX your request to (301) 402–1819, or E-mail your request, including your address, to Silvermd@exchange.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before June 26, 2000.

Dated: April 18, 2000.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 00–10403 Filed 4–25–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; 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 Board of Governors of the Warren Grant Magnuson Clinical Center.

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: Board of Governors of the Warren Grant Magnuson Clinical Center.

Date: June 5, 2000.

Time: 9 a.m. to 1:30 p.m.

Agenda: For discussion of planning and operational issues.

Place: National Institutes of Health, Clinical Center Medical Board Room, 2C116, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Maureen E. Gormley, Executive Secretary, Warren Grant Magnuson Clinical Center, National Institutes of Health, Building 10, Room 2C146, Bethesda, MD 20892, 301/496–2897.

Dated: April 19, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–10404 Filed 4–25–00; 8:45 am]

BILLING CODE 4140–01–M