b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

7. Dissemination—What plans have been articulated for disseminating findings?

A second programmatic review will be conducted by a panel of Senior Federal Officials. The Officials will review the ranked proposals to assure maximal impact and balance of the proposed research. The factors to be considered will include:

1. The results of the peer review.

2. The importance of the proposed research for meeting the primary goals of this initiative, as described in ''Program Requirements'' section.

3. Budgetary considerations.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities and Objectives.

b. Current Budget Period Financial Status.

c. New Budget Period Proposed Activities and Objectives.

d. Detailed Line-Item Budget and Justification for the new budget period.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of this announcement as posted on the CDC Web site.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–7 Executive Order 12372 Review

AR–8 Public Health System Reporting Requirements

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR–15 Proof of Non-Profit Status (if applicable)

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—*http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

Business management technical assistance may be obtained from: Merlin J. Williams, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2765, E-mail address: *MWilliams2@cdc.gov*.

For program technical assistance, contact: Anthony D. Moulton, PhD, Public Health Law Program, Public Health Program Practice Office, Centers for Disease Control and Prevention, 4770 Buford Hwy. (K–36), Atlanta, Georgia 30341–3724, Phone: 770–488–2405/Fax 770–488–2474, E-mail: *ADM6@CDC.GOV*.

Dated: April 11, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–9424 Filed 4–16–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., June 4, 2003; 8:30 a.m.–12 p.m., June 5, 2003.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333. Telephone (404) 639–8008.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis (TB). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating TB.

Matters to be Discussed: Agenda items include issues pertaining to improving TB control efforts in the Southeast, TB among the foreign born, and other TB-related topics.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Paulette Ford-Knights, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 11, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–9425 Filed 4–16–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0454]

Agency Information Collection Activities; Announcement of OMB Approval; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Notice of a Claim for Generally Recognized as Safe Exemption Based on

a Generally Recognized as Safe Determination'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 3, 2003 (68 FR 5294), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0342. The approval expires on April 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9383 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0009]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for Exemption From Federal Preemption of State and Local Medical Device Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the information collection provisions by May 19, 2003.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Application for Exemption From Federal Preemption of State and Local Medical Device Requirements—21 CFR Part 808 (OMB Control Number 0910–0129)—Extension

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)) provides that no State or local government may establish, or continue in effect, any requirement with respect to a medical device that is different from, or in addition to, any Federal requirement applicable to the device under the act. Under section 521(b) of the act, following receipt of a written application from the State or local government involved, FDA may exempt from preemption a requirement that is more stringent than the Federal requirement, or that is necessitated by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any portion of any requirement under the act. Exemptions are granted by regulation issued after notice and opportunity for an oral hearing.

The regulations in 21 CFR 808.20 require a State or local government that is seeking an exemption from preemption to submit an application to FDA. The application must include a copy of the State or local requirement, as well as information about its interpretation and application, and a statement as to why the applicant believes that the requirement qualifies for exemption from preemption under the act. FDA will use the information in the application to determine whether the requirement meets the criteria for exemption in the act and whether granting an exemption would be in the interest of the public health.

In addition, 21 CFR 808.25 provides that an interested person may request a hearing on an application by submitting a letter to FDA following the publication by FDA of a proposed response to the application.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Numbers of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
808.20	3	1	3	100	300
808.25	3	1	3	10	30
Total					330

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based its estimates of the number of submissions expected in the future contained in table 1 of this document on the number of submissions submitted in the last 3 years and on the number of inquiries received indicating that applications would be submitted in the next year. FDA based its estimates of the time required to prepare submissions on discussions with those who have prepared submissions in the last 3 years.

Dated: April 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9385 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S