Respondents	Number of respondents	Number of responses/ respondent	Average burden of response (in hrs.)	Total burden (in hrs.)
Health Care Providers	1800	1 D20/60	600	
Office Managers	1800	1	20/60	600
Totals				1200

Dated: September 27, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–25321 Filed 10–2–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Availability of Government-Owned Trademark for Licensing

AGENCY: National Institute of Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

TITLE: Availability of a Government-owned Trademark for Licensing: The Registry of Toxic Effects of Chemical Substances (RTECS®).

ACTION: Notice and request for proposals. NIOSH is requesting proposals for the purpose of establishing a licensing agreement for the continuation of a trademarked product: RTECS®. (The NIOSH Trademark named in this notice is owned by the United States Government and is available or licensing in the United States (U.S.), in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.)

SUMMARY: From the 1971 initial release of the mandated *Toxic Substances List,* the National Institute for Occupational Safety and Health (NIOSH) has been systematically building and updating the Registry of Toxic Effects of Chemical Substances (RTECS®). RTECS® was originally published in book format, later a microfiche version was developed. Currently, RTECS® is available in a digital format for electronic delivery. RTECS® is recognized as the world's most extensive collection of numerical toxicological data. Because RTECS® identifies specific toxicological endpoints, it has a unique status among databases that provide toxicology information. RTECS® is used not only by the occupational safety and health community; it serves as a standard reference for life-science scientists and regulatory groups from all parts of the world. Both its content and design have contributed to its wild spread use, thus making RTECS® a commercially viable product. NIOSH is now soliciting proposals from organizations interested in assuming the responsibility for the continued operation and funding of RTECS®. This include the ongoing review of toxicological documents, extraction and updating of appropriate information as well as the marketing and distribution of the RTECS® database through a trademark licensing agreement.

DATES: Written licensing proposals can be sent to Thomas E. O'Toole, M.P.H., Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Mailstop E–67, 1600 Clifton Road, Atlanta, Georgia 30333 on or before December 4, 2000.

FOR FURTHER INFORMATION CONTACT: Doris Sweet, Education and Information Division, Information Resources Branch, NIOSH, CDC 4676 Columbia Parkway, Mailstop C–18, Cincinnati, Ohio 45226, telephone 513–533–8359, e-mail address: *dvs1@cdc.gov.*

SUPPLEMENTARY INFORMATION:

RTECS® Trademark License Proposal

1. Exclusive use of the RTECS® name for the production and marketing of the database. The Licensee will have unlimited right to the use of the RTECS® name for product identification and promotion as related to selling and marketing the production of the Database.

2. Control of the current RTECS® Master File. The Licensee will provided with a copy of the last NIOSH-produced RTECS® Master File and the CODEN File. The Licensee may reformat the data, provided the six toxicity fields remain intact. New fields may be added for the enhancement of the Database (*e.g.* physical and chemical properties, structural formulas, author names). Selected fields may be deleted if the worth or power of the Database is not diminished (*e.g.,* Wiswesser Line Notation).

3. Authority and responsibility for vendor agreements. Upon execution of this agreement, the National Technical Information Service (NTIS), currently serving as broker for NIOSH, will notify all current vendors that existing vendor agreements will terminate after ninety (90) days. Thereafter, vendor agreements become the responsibility of the Licensee, who may decide to extend existing agreements until the expiration date, or to negotiate new agreements with all vendors. The Licensee will not be bound by any previous agreements with NTIS, unless they chose to negotiate with that organization.

4. Access to comprehensive documentation. NIOSH will provide access to the collection of all source references cited in RTECS®. These are an essential tool in accessing the original documentation cited in the Database. In order to assure full historical information, NIOSH will also provide access to a complete collection of printed editions of RTECS®, from 1971 to 1985–86, and annual microfiche editions beyond 1987.

5. NIOSH consultation services. NIOSH will provide support to the Licensee through participation on any established Board/Committee empowered to modify the Database.

NIOSH Requirements To Be Addressed in the Proposal

1. Maintenance of RTECS® as a viable toxicological database. The Licensee must maintain the quality of the Database, making only such changes that will enhance its value and power, and those mandated by changing technologies. The adoption of alternate test methods will require an altered approach. The proposal should address plans for coverage of current toxicological literature on an international scale.

2. Preservation of international literature coverage. The proposal shall address the manner in which the continued coverage of international literature will be accomplished. Because much of the current data now originates from outside the United States, especially in the Orient and Eastern Europe, access to linguistic skills is vital.

3. Continued accessibility of RTECS® to the international scientific community. The Licensee must make RTECS® continuously available world-wide and market the Database in a variety of formats including, but not limited to on-line, CD–ROM, and the Internet.

4. Multiple point and free access to NIOSH of all RTECS® products. The Licensee will provide NIOSH research and information staff with multiple point and free access to RTECS® to accommodate NIOSH users at six NIOSH sites, maximum usage not to exceed 25 users.

5. NIOSH representation on editorial or policy board or committee. A NIOSH representative will be designated to serve on any editorial or policy board established for the Database to ensure that the interests of the Institute are considered. This representative will serve in a consultative capacity without decision-making authority.

General Terms

1. Ownership of the RTECS® trademark will be retained by NIOSH.

2. The licensing agreement can be terminated by either party.

3. Ownership of data files, microfiche, and other files. NIOSH will retain ownership of the last RTECS® Master File produced with NIOSH funds. The Licensee will retain ownership of all new data generated and indexed under this agreement. NIOSH will also retain ownership of the microfiche collection of the bibliographical references. The full hard copy collection of the same references will be delivered to the Licensee, along with the annual microfiche editions produced after 1987. In the event of a termination of the Licensing Agreement, the hard copy collection and annual microfiche additions will be returned to NIOSH.

4. Duration of agreement will be negotiated in the license.

5. In submitted proposals, each requirement shall be addressed individually.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 00–25429 Filed 10–02–00; 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 (P.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., October 18, 2000; 8:30 a.m.–12 p.m., October 19, 2000.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333.

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. 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 tuberculosis.

Matters To Be Discussed: Agenda items include issues pertaining to the IOM Report on TB Elimination in the U.S. and other TB related topics.

Contact Person for More Information: Paulette Ford, 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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 27, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–25322 Filed 10–2–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1224]

Agency Information Collection Activities; Announcement of OMB Approval; Submitting and Reviewing Complete Responses to Clinical Holds; Guidance for Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Submitting and Reviewing Complete Responses to Clinical Holds; Guidance for Industry'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April, 13, 2000 (65 FR 19910), 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 0910–0445. The approval expires on September 12, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 26, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–25283 Filed 10–2–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.