

## Other Requirements

### *Paperwork Reduction Act*

Projects that involve the collection of information from ten or more individuals and funded by this cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

### *Human Subjects*

If the proposed project involves research on human subjects, the applicant must comply with the DHHS Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

### *Women, Racial and Ethnic Minorities*

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

## Application Submission and Deadline

### *A. Preapplication Letter of Intent*

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to Victoria F. Sepe, Grants Management Specialist, Grants Management Branch, CDC at the address listed in this section. It should be postmarked no later than July 11, 1997. The letter should identify the Program Announcement number 757 and the name of principal investigator. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

### *B. Application*

The original and four copies of the application PHS Form 398 (Revised 5/95, OMB Number 0925-0001) must be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E-13, 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, on or before July 25, 1997.

1. *Deadline:* Applications will be considered as meeting the deadline if they are either:

- (a) Received on or before the deadline date, or
- (b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. *Late Applicants:* Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

### **Where To Obtain Additional Information**

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement 757. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 757 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E-13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842-6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Lynne E. Pinkerton, M.D., M.P.H., Medical Officer, Epidemiology 1 Section, Industrywide Studies Branch, Division of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop R-15, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 841-4344, Internet: lep5@cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction section through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: <http://www.cdc.gov>.

Dated: June 4, 1997.

**Diane D. Porter,**

*Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97-15179 Filed 6-10-97; 8:45 am]

BILLING CODE 4163-19-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Announcement 738]

### National Institute for Occupational Safety and Health; Assessment of Respiratory Exposure Hazards in Composting

#### Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997

funds for a cooperative agreement to conduct cross-sectional studies at composting facilities of respiratory exposures and respiratory health effects among compost workers.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of Healthy People 2000, see the section **Where to Obtain Additional Information.**)

CDC, National Institute for Occupational Safety and Health (NIOSH) is committed to the program priorities developed by the National Occupational Research Agenda (NORA). (For ordering a copy of the NORA, see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

#### **Authority**

This program is authorized under Sections 20(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a) and 671(e)(7)).

#### **Smoke-Free Workplace**

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

#### **Eligible Applicants**

Applications may be submitted by public and private, non-profit and for-profit organizations and governments, and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

**Note:** Public Law 104-65, dated December 19, 1995, prohibits an organization described in section 501(c)(4) of the IRS Code of 1986, that engages in lobbying activities to influence the Federal Government, from receiving Federal funds.

#### **Availability of Funds**

Approximately \$200,000 will be available in FY 1997 to fund up to two awards at approximately \$100,000 each. It is expected that the awards will begin

on or about September 30, 1997, and will be made for 12-month budget periods within the project period of up to 3 years. The funding estimate is subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

#### **Use of Funds**

##### *Restrictions on Lobbying*

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or "grass roots" lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104-208, provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, \* \* \* except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997,

Division A, Title I, Section 101(e), Pub. L. No. 104-208 (September 30, 1996).

#### **Background**

Composting is the decomposition of organic materials under aerobic conditions which produces a stable, humus-like material which can be used as a soil amendment. Materials composted can include yard waste, food/household waste, food processing waste, agricultural wastes, biosolids, and animal wastes. The recycling of biosolids and the organic fractions of municipal solid waste is increasing because of the benefits that can arise and because the disposal alternatives such as land filling and incineration are more costly, unpopular, or restricted by law. The consequence of this is a dramatic increase in the number of composting operations and the number of workers exposed to organic dusts at these facilities. The proceedings from a national composting council workshop indicate that there were approximately 2500 composting facilities operating in the United States during 1992 with a large expected growth rate (over 45 percent) in the number of composting facilities during subsequent years. The rapid growth in this industry, combined with the potential for worker exposure to organic dusts containing many toxic and immunogenic constituents, indicates the need for studies to address potential respiratory health problems among workers in this industry. Upper respiratory tract irritation, organic dust toxic syndrome (ODTS), asthma, bronchitis, and hypersensitivity pneumonitis are among the respiratory health problems described to occur from organic dust exposures such as those associated with composting.

Composting is an emerging technology area. Under the NIOSH National Occupational Research Agenda (NORA), emerging technologies represent a priority area for research efforts to (1) Assess their potential to cause harm to workers, (2) evaluate specific worksites, (3) develop effective control strategies where occupational hazards exist, (4) identify superior new technologies that diminish risk, and (5) share information for the benefit of all persons at risk and those responsible for managing the risk.

This project addresses many of these emerging technology criteria described in NORA.

#### **Purpose**

The purpose of this project is to conduct research to identify potential exposure hazards and respiratory health problems among workers in the composting industry. This information

will be used to promote respiratory health for this workforce and direct prevention efforts as appropriate.

The specific objectives for this cooperative agreement program include the following: develop a research protocol(s) for a cross-sectional study of respiratory exposures and respiratory health effects among workers employed at composting facilities; conduct in-depth environmental investigations of respiratory exposure hazards at selected composting facilities; conduct in-depth clinical investigations on the respiratory health status of workers at selected composting facilities; and describe the composting processes used at each survey site including the control procedures used to reduce worker exposures.

**Note:** Protocols should exclude sampling sites in Department of Health and Human Services (DHHS) Region VII from the sample (DHHS Region VII includes the following States: Iowa, Kansas, Missouri, and Nebraska). This exclusion is to avoid duplication with ongoing composting research efforts completed through the NIOSH funded Centers for Agriculture Research, Education and Disease Injury and Prevention in DHHS Region VII.

#### **Program Requirements**

In conducting activities to achieve the purpose of this agreement, the recipient will be responsible for conducting activities under A. (Recipient Activities) below, and CDC/NIOSH will be responsible for conducting activities under B. (CDC/NIOSH Activities) below:

##### *A. Recipient Activities*

1. Develop a research protocol(s) for a cross-sectional study of respiratory exposures and respiratory effects among workers employed at composting facilities. Obtain scientific peer review of the protocol(s), revise, and finalize the protocol(s).

2. Conduct a comprehensive environmental investigation of respiratory exposure hazards at selected composting facilities. Personal and area environmental sampling data collected from each of these facilities should include, at a minimum, particulate not otherwise regulated (formerly known as "total dust"), metals, endotoxins, viable microorganisms, and ammonia.

3. Conduct in-depth clinical investigations on the respiratory health status of workers at selected composting facilities. Study design should take into account sources of bias in particular the problems encountered when limiting the study to current employees. Clinical investigations should include, at a minimum:

a. The development and administration of a questionnaire

designed to gather information on work and exposure history and respiratory health effects. The questionnaire should be administered to all members of this study population.

b. The development and implementation of a pulmonary function testing program appropriate to the investigation of respiratory health effects among compost workers at selected facilities.

4. Clarify the composting processes used at each survey site including the control procedures used to reduce worker exposures.

5. Collaborate with CDC/NIOSH scientists on study research efforts.

6. Report and disseminate, if desired, research results and relevant health and safety education and training information to appropriate health care providers, the scientific community, agricultural workers and their families, management and union or other worker representatives, and Federal, State, and local agencies. Emphasis should be placed on the rapid dissemination of significant public health findings and the translation of research findings into prevention efforts.

##### *B. CDC/NIOSH Activities*

1. Provide technical assistance in the areas of program development and study research efforts, implementation, maintenance.

2. Provide technical assistance, if needed, related to the development and implementation of the pulmonary function testing program.

3. Provide technical assistance, if needed, related to the collection, review and/or analysis of data.

4. Collaborate in the reporting and dissemination of research results and relevant health and safety education and training information.

#### **Technical Reporting Requirements**

An original and two copies of semi-annual progress reports are required. Timelines for the semi-annual reports will be established at the time of award. Final financial status and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Semi-annual progress report should include:

A. A brief program description.

B. A listing of program goals and objectives accompanied by a comparison of the actual accomplishments related to the goals and objectives established for the period.

C. If established goals and objectives to be accomplished were delayed,

describe both the reason for the deviation and anticipated corrective action or deletion of the activity from the project.

#### **Application Content**

The entire application, including appendices, should not exceed 40 pages and the Proposal Narrative section contained therein should not exceed 25 pages. Pages should be clearly numbered and a complete index to the application and any appendices included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with un-reduced type (font size 12 point) on 8½" by 11" paper, with at least 1" margins, headers, and footers, and printed on one side only. Do not include any spiral or bound materials or pamphlets.

The applicant should provide a detailed budget, with accompanying justification of all operating expenses, that is consistent with the stated objectives and planned activities of the project. CDC may not approve or fund all proposed activities. Applicants should be precise about the program purpose of each budget item. For contracts described within the application budget, applicants should name the contractor, if known; described the services to be performed and provide an itemized breakdown and justification for the estimated cost of the contract; the kinds of organizations or parties to be selected; the period of performance; and the method of selection. Place budget narrative pages showing, in detail, how funds in each object class will be spent, directly behind form 424A. Do not put these pages in the body of the application.

The applicant should provide a detailed description of first-year activities and briefly describe future-years objectives and activities.

##### *A. Title Page*

The heading should include the title of grant program, project title, organization, name and address, project director's name address and telephone number.

##### *B. Abstract*

A one page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director and telephone number. This abstract should include a work plan identifying activities to be developed, specific activities to be

completed, and a time-line for completion these activities.

### C. Proposal Narrative

The narrative of each application must:

1. Briefly state the applicant's understanding of the need or problem to be addressed and the purpose of this cooperative agreement. This should include a draft protocol for the study. The protocol(s) should include:

(a) A sampling strategy to insure that a representative sample of composting operations and technologies are included in the study, and

(b) The sampling strategy should maximize the number of study sites and include a representative sample based on geographic considerations.

2. (a) Describe clearly the objectives of this project, the steps to be taken in planning and implementing this project, and the respective responsibilities of the applicant for carrying out those steps.

(b) Provide a proposed schedule for accomplishing each of the activities to be carried out in this project and a method of evaluating the accomplishments.

3. Provide documentation of access to potential study sites with the sample characteristics specified, and provide documentation of management and labor representatives to participate in the intervention study.

4. Document the applicant's expertise in the area of exposure and health assessment as they pertain to occupational safety and health.

5. Provide the name, qualifications, and proposed time allocation of the Project Director who will be responsible for administering the project. Describe staff, experience, facilities, equipment available for performance of this project, and other resources that define the applicant's capacity or potential to accomplish the requirements stated above. List the names (if known), qualifications, and time allocations of the existing professional staff to be assigned to (or recruited for) this project, the support staff available for performance of this project, and the available facilities including space.

6. Human Subjects: State whether or not Humans are subjects in this proposal. (See *Human Subjects* in the Evaluation Criteria and Other Requirements sections.)

7. Inclusion of women, ethnic, and racial groups:

Describe how the CDC policy requirements will be met regarding the inclusion of women, ethnic, and racial groups in the proposed research. (See *Women, Racial and Ethnic Minorities* in

the Evaluation Criteria and Other Requirements sections.)

8. Provide a detailed budget which indicates: (a) anticipated costs for personnel, travel, communications, postage, equipment, supplies, etc., and (b) all sources of funds to meet those needs.

### Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

#### A. Background and Need (20%)

Responsiveness to the purpose of this project, including the applicant's understanding of the objectives of the proposed cooperative agreement and the relevance of the proposal to the objectives.

#### B. Goals, Objectives and Methods (25%)

1. The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable. The extent to which the methods are sufficiently detailed to allow assessment of whether the objectives can be achieved for the budget period. The extent to which a qualified plan is proposed that will help achieve the goals stated in the proposal.

2. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. This includes: (a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (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; and (d) A statement as to whether the plan for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

#### C. Strength of Programs (20%)

Strength of the applicant's environmental and clinical research programs including a demonstrated ability in the conduct of occupational health studies involving organic dusts, gases, and respiratory health assessment.

#### D. Project Management and Staffing Plan (20%)

Training and experience, qualifications, and time commitment of the project director, staff, and organization. This includes a Project director who is a distinguished scientist

and technical expert and staff with the necessary training and experience sufficient to accomplish proposed project.

#### E. Experience/Expertise (10%)

Applicant's knowledge/understanding and experience in the composting industry.

#### F. Facilities and Resources (5%)

Efficiency of resources and novelty of program. This includes the efficient use of existing and proposed personnel with assurances of a major time commitment of the Project Director to the program and the novelty of program approach.

#### G. Human Subjects (Not Scored)

Whether or not exempt from the DHHS regulations, are procedures adequate for protection of human subjects? Recommendations on the adequacy of protections include: (1) Protections appear adequate, and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Objective Review Group has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

#### H. Budget Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

### Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit.

If SPOCs have any State process recommendations on applications submitted to CDC, they should be sent to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers

for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, no later than September 1, 1997. The Program Announcement Number 738 and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to: Victoria Sepe, Grants Management Specialist, Grants Management Branch, Centers for Disease Control and Prevention, 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, GA 30305. This should be done no later than September 1, 1997. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date.

#### **Public Health System Reporting Requirements**

This program is not subject to the Public Health System Reporting Requirements.

#### **Catalog of Federal Domestic Assistance Number**

The Catalog of Federal Domestic Assistance Number for this program is 93.262.

#### **Other Requirements**

##### *Paperwork Reduction Act*

Projects funded through the cooperative agreement mechanism of this program involving the collection of information from 10 or more individuals will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

##### *Human Subjects*

If the proposed project involves research on human subjects, the applicant must comply with the DHHS Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS)

institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

##### *Women and Minority Inclusion Policy*

It is the policy of the Centers for Disease Control and Prevention (CDC) to ensure that women and racial and ethnic groups will be included in CDC supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority population are appropriately represented for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance on this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951.

#### **Application Submission and Deadline**

##### *A. Preapplication Letter of Intent*

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, CDC at the address listed in this section. It should be postmarked no later than July 1, 1997. The letter should identify Program Announcement 738 and name of the principal investigator. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

##### *B. Application*

The original and two copies of the application PHS Form 5161-1 (Revised

7/92, OMB Number 0937-0189) must be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, on or before July 18, 1997.

1. *Deadline:* Applications will be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. *Late Applicants:* Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicants.

#### **Where to Obtain Additional Information**

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement 738. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to NIOSH Announcement Number 738 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E-13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842-6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Patrick Hintz, M.S., Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop P04/111, 1095 Willowdale Road, Morgantown, WV 26505-2888, telephone (304) 285-5744, Internet: pjhl@cdc.gov.

This and other CDC announcements are available through the CDC homepage

on the Internet. The address for the CDC homepage is: <http://www.cdc.gov>.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the **Introduction** section through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

The National Occupational Research Agenda: copies of this publication may be obtained from the National Institute for Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226-1998 or telephone 1-800-356-4674, and is available through the NIOSH Home Page; <http://www.cdc.gov/niosh/nora.html>.

#### NORA Priority Research Areas

##### Disease and Injury

- Allergic and Irritant Dermatitis
- Asthma and Chronic Obstructive Pulmonary Disease
- Fertility and Pregnancy Abnormalities
- Hearing Loss
- Infectious Diseases
- Low Back Disorders
- Musculoskeletal Disorders of the Upper Extremities
- Traumatic Injuries

##### Work Environment and Workforce

- Emerging Technologies
- Indoor Environment
- Mixed Exposures
- Organization of Work
- Special Populations at Risk

##### Research Tools and Approaches

- Cancer Research Methods
- Control Technology and Personal Protective Equipment
- Exposure Assessment Methods
- Health Services Research
- Intervention Effectiveness Research
- Risk Assessment Methods
- Social and Economic Consequences of Workplace Illness and Injury
- Surveillance Research Methods

Dated: June 4, 1997.

#### Diane D. Porter,

*Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97-15180 Filed 6-10-97; 8:45 am]

BILLING CODE 4163-19-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0212]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Extension

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the electronic collection of data by FDA regarding FDA-regulated products of foreign origin that are being offered for import into the United States.

**DATES:** Submit written comments on the collection of information by August 11, 1997.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Importer's Entry Notice—(OMB Control Number 0910-0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Assuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of the goods to their final destination; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Customs Service. FDA uses the information to make admissibility decisions about