Respondent: one; *Average Burden per Response:* 5 minutes; *Total Burden for Intake Form:* 830 hours—Burden Information for the Contact Information Form—*Number of Respondents:* 10,000; *Number of Responses per Respondent:* one; *Average Burden per Response:* 3 minutes; *Total Burden for Contact Information Form:* 500 hours—Burden Information for the Consent Form—*Number of Respondents:* 10,000; *Number of Responses per Respondent:* one; *Average Burden per Response:* 2 minutes; *Total Burden for Consent Form:* 330 hours. Total Burden: 1,660 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC, 20201. Written comments should be received within 60 days of this notice.

Dated: November 23, 1998.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 98–31863 Filed 11–30–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The Health Impact of Chemical Exposure During the Gulf War: A Research Planning Conference

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC), in coordination with the Office of Public Health and Science (Department of Health and Human Services), the National Institutes of Health, and the Agency for Toxic Substances and Disease Registry announces the following meeting:

Name: The Health Impact of Chemical Exposures During the Gulf War: A Research Planning Conference.

Times and Dates: 8 a.m.–9 p.m., February 28, 1999. 8 a.m.–10 p.m., March 1, 1999. 8 a.m.–12 noon, March 2, 1999.

Place: Crowne Plaza Hotel—Atlanta Airport, 1325 Virginia Avenue, Atlanta, Georgia 30344. Telephone 404/768–6660.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 500 people.

Purpose: The purpose of this conference is to provide a forum for broad public input into the development of a multi-year research plan for investigating the relationship between chemical exposures during the Gulf War and illnesses affecting Gulf War veterans.

Matters To Be Discussed: Agenda items include a discussion of the current research findings on the health impact of the Gulf War; a panel discussion of the experience of Gulf War veterans; possible health outcomes of low level chemical exposures; research and clinical findings regarding multiple chemical sensitivity among Gulf War veterans and civilian populations; possible mechanisms of action of chemical exposures; methodological considerations in studying the health impact of chemical exposures during the Gulf War.

Concurrent workgroups will be held to develop research recommendations in the areas of pathophysiology/etiology of illnesses among Gulf War veterans; the most appropriate methods for assessing and diagnosing the health impact of chemical exposures; the most appropriate treatment approaches; and the prevention of similar illnesses in future military deployments.

There will be a special Veterans Forum on Sunday, February 28, 1999 at 7:00 p.m. This will serve as an opportunity for veterans to provide input regarding research priorities. In addition, a social is scheduled for 8:00 p.m. on Monday, March 1, 1999. Additional information and registration material is available at our website: http://www.cdc.gov/nceh/meetings/1999/gulfwar/.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Phillip M. Talboy, Deputy Chief, Veterans' Health Activity Working Group, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), m/s F–28, 4770 Buford Highway, NE, Atlanta, Georgia 30341–3724. Telephone 770/488–3546, e-mail,pmt0@cdc.gov.

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: November 24, 1998.

Julia M. Fuller,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–31908 Filed 11–30–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84G–0218]

American Feed Industry Association; Withdrawal of Generally Recognized as Safe (GRAS) Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of the petition (GRASP MF–3891) proposing affirmation that selenium (as sodium selenite or selenate) is generally recognized as safe (GRAS) when used in animal feeds as a nutritional supplement in accordance with current good manufacturing and feeding practices. The petition also proposes removal of the selenium food additive regulation.

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6657.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 29, 1984 (49 FR 26814), FDA announced that a GRAS affirmation petition (GRASP MF–3891) had been filed by American Feed Manufacturers Association, Inc., 1701 North Fort Myer Dr., Arlington, VA 22209. The American Feed Manufacturers Association, Inc., has since changed its name and address to American Feed Industry Association, 1501 Wilson Blvd., suite 1100, Arlington, VA 22209. The petition proposed to: (1) Amend the regulations for affirmation of GRAS status in part 582 (21 CFR part 582) of Subpart F—Nutrients and/or Dietary Supplements to affirm that selenium (as sodium selenite or selenate) is GRAS when used in animal feeds as a nutritional supplement in accordance with current good manufacturing and feeding practices and (2) remove the selenium food additive regulation at 21 CFR 573.920. The American Feed Industry Association has withdrawn the petition without prejudice to a future filing.

Dated: November 5, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–31853 Filed 11–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health; Office of the Director; Notice of Call for Nominations for the Director's Council of Public Representatives

The National Institutes of Health (NIH), the Federal government's primary agency for supporting and conducting medical research leading to the improvement in the nation's health, has established a new national advisory council—the Director's Council of Public Representatives (COPR). The Chair of the COPR is the Director of the National Institutes of Health. This notice lays out a process for the

selection of members of the first COPR and seeks nominations.

Background

On September 23, 1998, the NIH Director chaired a meeting on public participation in NIH activities (FR Doc. 98–24463 Filed 9–10–98; 8:45 a.m.). At the meeting, 23 individual public participants invited by the NIH discussed future activities and responsibilities of the proposed NIH Director's Council of Public Representatives (COPR), which will serve as a forum for discussing issues and concerns and exchanging viewpoints that are important to NIH policies, programs, and research priorities. The individual participants at the meeting also discussed the processes, mechanisms, and criteria that should be used for identifying appropriate candidates to serve on the COPR. A notice about the creation of the COPR was published in the **Federal Register** on November 17, 1998 (FR Doc. 98–30695 Filed 11–16–98; 8:45 a.m.).

The COPR will help bring to NIH the concerns and interests of the many external publics that have a stake in the agency's activities, programs, policies, and research. In addition to serving as a forum, the COPR will assist the NIH in enhancing the participation of the public in myriad NIH activities that have an impact upon the public, in increasing public understanding of the NIH and its programs, and in bringing important matters of public interest forward for discussion in public settings.

The COPR will consist of up to 20 individuals who have an interest in the NIH's mission. The NIH will bring together these individuals from diverse backgrounds approximately twice each year, enabling them to interact directly with NIH leaders on a wide range of programs and issues. In addition to these two meetings annually, the COPR may suggest other activities, subject to approval by the Chair of the COPR, the Director of the NIH. Members of the first COPR will serve one, two, or three-year terms. In subsequent years, members will serve three-year terms.

Eligibility Requirements for Individual Members

To serve on the COPR, an individual must meet the following *minimum* eligibility requirements:

- Have some interest in the work of the NIH, for example, as a patient or family member of a patient; a health care professional; a member of a patient advocacy group; an individual who works as a volunteer in the health field; a scientist or a student of science; a communicator in health, medicine, or science; an individual in public service, academia, or in a professional society touching the medical field. These examples are not meant to limit nominations to those listed—any member of the public with special interests in the NIH may be nominated or may nominate themselves.
- Be in a position (formally or informally) to communicate regularly with the broader public or segments of the public about the activities of the COPR and the NIH.

Another essential requirement is a commitment to participating fully in activities of the COPR, including possibly in subcommittee activities that may take time in addition to meeting attendance. In addition, members—while participating in COPR activities—will have to agree to subordinate disease-specific or program-specific interests to broader, cross-cutting matters of importance to the NIH and its commitment to public representation. These additional requirements will not be used in the initial screening of nominees, but will be assessed as part of a more in-depth evaluation of qualified candidates.

A. Criteria for Evaluating Individual Candidates

Nominees who meet the minimum eligibility requirements will be further assessed on the following criteria:

1. Interest in NIH's research, programs, activities, and policies broadly, and some understanding of, or familiarity with, the NIH mission and medical science.
2. Ability to communicate effectively.
3. Ability to consider broad issues and think ''globally,'' beyond narrow personal or professional interests.
4. Ability to contribute to an effective group process (e.g., cooperative, constructive, flexible, innovative).
5. Leadership ability (members of the COPR are not required to hold a formal leadership position within any organized group, but must have leadership skills).
6. Understanding of, and ability to express or represent, a ''public'' view of issues.
7. Ability to identify a problem, analyze it, and put forth solutions.

B. Characteristics of the COPR as a Group

In addition to the criteria for individual candidates, the following characteristics of the COPR as a group are intended to ensure that it reflects the breadth and diversity of the publics interested in the NIH:

1. Multi-cultural diversity.
2. A broad spread across the various ''publics'' interested in the NIH (see examples cited in the minimum eligibility requirements above).
3. Representation of the medically underserved (examples might include the medically uninsured or underinsured, people who for various reasons do not have adequate access to good medical care, and people who do not take advantage of available medical services).
4. A range of organizations (if applicable), local/regional and national.
5. Men and women.
6. Age diversity.
7. Geographic diversity (rural/urban mix; nationwide spread).

Screening, Scoring and Review Process

After nominees are screened for basic eligibility they will be reviewed and scored in terms of the criteria for evaluating individual candidates (as listed in section A.1–7) by external people familiar with the responsibilities of the COPR. A list of highly qualified candidates who reflect balance and diversity of representation will be forwarded to the Director of NIH for selection of COPR members. The Director may determine to interview candidates (possibly in groups) prior to final selection.

Nomination Process

The call for nominations is being disseminated through this **Federal Register** notice and through ancillary distribution to a broad range of groups, including national organizations, to encourage nominations of candidates reflecting the diversity sought for the COPR.

Nominations may come from organizations or from individuals. Self-nominations will be accepted. Interviews may be conducted with the most qualified candidates during the selection process.

Each nomination package must include:

1. A brief cover letter stating why the individual nominated wants to be a member of the COPR and comments about what they can contribute to fulfilling the mission of the COPR. This letter should address the individual's particular interests in the work of the NIH. Because the COPR will represent the varied publics served by NIH, it will be important to include information about the public, or segments of the public, with which the nominee would communicate, i.e., describe the group briefly in terms of geographic location, age, gender, ethnicity, whether or not the group includes the medically

underserved, and if it is local, regional, or national (for guidance, see characteristics of the COPR and minimum eligibility requirements above).

2. Brief comments relevant to *each* of the 7 criteria cited above under A. 1–7. All 7 criteria should be addressed in no more than 3 pages.

3. Two letters of recommendation from individuals familiar with the nominee (these individuals may be contacted during the selection process).

4. A statement of assurance that, if selected, the individual will: (a) agree to participate fully in activities of the COPR, and (b) subordinate individual disease-specific or program-specific interests to broader, cross-cutting matters of importance to the NIH and its commitment to public representation.

5. *If the nomination is from a third party*, verification that the individual nominated is cognizant that he or she is being nominated and wishes to be considered for membership on the COPR.

The items noted above in ''Nomination Process'' (1–5) should be mailed to: Palladian Partners, Inc., Call for Nominations (COPR), 7315 Wisconsin Avenue, Suite 440W, Bethesda, Maryland 20814. Nominations must be postmarked by the January 15, 1999, closing date. Incomplete or late nomination packages will not be considered. If you have any questions, please call the NIH Office of Communications [and Public Liaison] at the National Institutes of Health: (301) 496–4461.

Final selections will be made by the NIH Director. The schedule calls for contacting selected members in February 1999. The first COPR meeting is planned for late April 1999.

Dated: November 19, 1998.

Anne Thomas,

Associate Director for Communications, NIH.

[FR Doc. 98–31919 Filed 11–30–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Opportunity for a Cooperative Research and Development Agreement (CRADA) to Develop Eosinophil-Derived Neutralizing Agent (EDNA) to Treat Infections in Children and the Elderly Caused by Respiratory Syncytical Virus and Parainfluenza Virus

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) is seeking capability statements from parties interested in entering into a Cooperative Research and Development Agreement (CRADA) to develop eosinophil-derived neutralizing agent (EDNA) for the treatment of infections in children and/or the elderly caused by respiratory syncytical virus (RSV) and parainfluenza virus (PIV). RSV and PIV are medically the most important single-stranded enveloped RNA viruses; infections caused by these viruses hospitalize over 100,000 infants per year in the U.S.

EDNA is the major eosinophil ribonuclease. Recombinant human EDNA is envisioned as an agent for direct inhalation therapy in patients with established RSV or PIV bronchiolitis, in those with a high index of suspicion, and as prophylactic therapy in children with predisposing conditions (prematurity, bronchopulmonary, dysplasia, congenital heart disease, and immunodeficiency).

Recombinant human EDNA has been produced in bacterial and baculovirus expression systems and is not toxic to respiratory epithelial cells. ENDA is a soluble and thermostable low molecular weight protein not requiring demanding conditions for storage or administration. *In vitro* experiments have shown it to have potent antiviral activity against RSV (Domachowske, JB et al. 1998. J. Infect. Dis. 177:1458–1464). Initial studies in the Balb/C mouse model of RSV infection support its effectiveness against this virus. This project is part of the study of ribonucleases and host defense in the Laboratory of Host Defenses (LHD), Division of Intramural Research, NIAID.

DATES: Only written capability statements received by the NIAID on or before March 1, 1999 will be considered.

ADDRESSES: Capability statements should be submitted to Dr. Michael R. Mowatt, Office of Technology Development, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 31 Center Drive MSC 2137, Building 31, Room 3B62, Bethesda, MD 20892–2137; Tel: 301/496–2644, Fax: 301/402–7132; Electronic mail: mmowattanih.gov.

SUPPLEMENTARY INFORMATION: Under the CRADA the production of biologically active recombinant human EDNA will be optimized and the agent evaluated in a series of preclinical studies in animals as well as initial safety testing in humans. Positive outcomes of these studies will indicate continued clinical development aimed at supporting regulatory approval of a product to be labeled for use in children and/or the elderly. The Public Health Service (PHS) has filed patent applications both in the U.S. and internationally related to this technology. Notice of the availability of the patent application for licensing was first published in the **Federal Register** (Vol. 62, No. 219, page 60909) on November 13, 1997.

NIAID's principal investigator has extensive experience with recombinant technology as applied to ribonucleases, their purification and testing. The Collaborator in this endeavor is expected to assist NIAID in evaluating its current system for producing recombinant EDNA and to develop and optimize an alternative expression system, if necessary, to manufacture sufficient quantities of the product for preclinical testing in animals and initial safety studies in humans. The Collaborator must have experience in the manufacture of recombinant protein products according to applicable FDA guidelines and Points to Consider documents to include Good Manufacturing Procedures (GMP). In addition, it is expected that the Collaborator would provide funds to supplement the LHD's research budget for the project and to support the preclinical and initial human testing.

The capability statement should include detailed descriptions of: (1) Collaborator's expertise in the expression of recombinant proteins, (2) Collaborator's ability to manufacture sufficient quantities of the product according to FDA guidelines and Points to Consider documents, (3) the technical expertise of the Collaborator's principal investigator and laboratory group in preclinical safety testing (e.g., expertise in *in vitro* and *in vivo* toxicity and