

for any claim that a food, drug, or supplement restores bone strength, reduces or eliminates pain associated with bone ailments, or is superior to any other form of calcium in bioavailability, absorbability, utilization by the body, or treatment or prevention of bone ailments.

In advertising or selling any food drug, or supplement, Part II forbids respondents from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test or study. In making claims regarding the relationship between calcium and osteoporosis, Part III requires respondents to limit themselves to the health claims authorized by the Food and Drug Administration, as set forth in 58 FR 2665 (1993), or to have competent and reliable scientific evidence to support the claims.

Part IV requires respondents to possess competent and reliable scientific evidence to support health-related claims for products containing calcium, and to have scientific substantiation for health-related superiority claims for any food, drug, or supplement.

Part V allow respondents to make representations that are specifically permitted by FDA regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990. Part VI allows respondents to make any claim for a drug that is permitted in labeling for that drug under any tentative or final FDA standard or under any FDA-approved new drug application.

Parts VII through X relate to respondents' obligations to make available to the Commission materials substantiating claims covered by the order; to notify the Commission of changes in Metagenics's corporate structure; to notify the Commission of changes in Mr. Katke's employment or business affiliations; and to provide copies of the orders to certain Metagenics personnel. Part XI provides that the order will terminate after twenty years under certain circumstances. Part XII requires respondents to file periodic compliance reports with the Commission.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 97-10971 Filed 4-28-97; 8:45 am]

BILLING CODE 6750-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Findings of Scientific Misconduct

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Office of Research Integrity (ORI) has made a final finding of scientific misconduct in the following case.

*Ann Marie Huelskamp, M.H.S., The Johns Hopkins University School of Medicine*

Based upon a report forwarded to the Office of Research Integrity (ORI) by The Johns Hopkins University School of Medicine, information obtained by ORI during its oversight review, and Ms. Huelskamp's own admission, ORI found that Ms. Huelskamp, a research program coordinator in the Oncology Center, The Johns Hopkins University School of Medicine, engaged in scientific misconduct by fabricating patient interview data for a study of quality of life measures in cancer patients. The research was supported by a grant from the National Cancer Institute (NCI), National Institutes of Health (NIH).

ORI also found that Ms. Huelskamp engaged in scientific misconduct by falsifying patient status data by failing to update the status of treated breast cancer patients and misrepresenting data from previous contacts as the updated status for a study. These data were reported in a grant application to NCI and gave the appearance that some patients' outcomes were more favorable than they actually were.

Ms. Huelskamp cooperated fully with the Johns Hopkins investigation. The investigation report acknowledged her excessive workload, the difficulties associated with recruiting and following up on patients, and a lack of supervisory oversight.

Ms. Huelskamp has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which she has voluntarily agreed, for the three (3) year period beginning April 17, 1997:

(1) To exclude herself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That any institution that submits an application for PHS support for a research project on which Ms. Huelskamp's participation is proposed or which uses her in any capacity on PHS-supported research must concurrently submit a plan for

supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Ms. Huelskamp's research contribution. The institution must submit a copy of the supervisory plan to ORI.

No scientific publications were required to be corrected as part of this Agreement.

#### FOR FURTHER INFORMATION CONTACT:

Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700 Rockville, MD 20852 (301) 443-5330.

**Chris B. Pascal,**

*Acting Director, Office of Research Integrity.*

[FR Doc. 97-10977 Filed 4-28-97; 8:45 am]

BILLING CODE 4160-17-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Agency for Toxic Substances and Disease Registry

[Announcement 803]

#### Public Health Conference Support Grant Program

##### Introduction

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the expected availability of funds in fiscal year (FY) 1998 for the Public Health Conference Support Grant Program.

CDC and ATSDR are 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 all of the Healthy People 2000 priority areas, except HIV Infection. (An announcement for HIV entitled, "Public Health Conference Support Cooperative Agreement Program for Human Immunodeficiency Virus (HIV) Prevention" will be published.) (For ordering a copy of "Healthy People 2000," see the Section "Where To Obtain Additional Information.")

##### Authority

The CDC program is authorized under Section 301 [42 U.S.C. 241] of the Public Health Service Act. The ATSDR program is authorized under Sections 104(i)(14) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, [42 U.S.C. 9604 (i)(14) and (15)].

### Smoke-Free Workplace

CDC and ATSDR strongly encourage all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and Pub. L. 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

CDC eligible applicants include public and private (e.g., community-based, national and regional organizations) nonprofit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private non-profit organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority and/or women-owned non-profit businesses are eligible for these grants.

ATSDR eligible applicants are the official public health agencies of the States, or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Island, the Republic of Palau, and federally recognized Indian tribal governments. State organizations, including State universities, State colleges, and State research institutions, must establish that they meet their respective State's legislature definition of a State entity or political subdivision to be considered an eligible applicant.

**Note:** Effective January 1, 1996, Pub. L. 104-65 states that an organization described in section 501 (c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

### Availability of Funds

Approximately \$500,000 from CDC is expected to be available in FY 1998 to fund approximately 25-30 awards. The awards range from \$1,000 to \$30,000 with the average award being approximately \$15,000. The awards will be made for a 12-month budget and project period. The funding estimates may vary and are subject to change, based on the availability of funds.

ATSDR expects to have approximately \$50,000 available in FY 1998 to fund approximately six awards.

It is expected that the average award will be \$8,000, ranging from \$5,000 to \$10,000. Applications requesting funds in excess of \$10,000 may not be fully funded, depending upon availability of funds. The awards will be made for a 12-month budget and project period. Funding estimates may vary and are subject to change.

### Use of Funds

- CDC and ATSDR funds may be used for direct cost expenditures: salaries, speaker fees, rental of necessary equipment, registration fees, and transportation costs (not to exceed economy class fare) for non-Federal individuals.

- CDC and ATSDR funds may not be used for the purchase of equipment, payments of honoraria, alterations or renovations, organizational dues, entertainment or personal expenses, cost of travel and payment of a Federal employee, nor per diem or expenses other than local mileage for local participants.

- CDC and ATSDR funds may not be used for reimbursement of indirect costs.

- Although the practice of handing out novelty items at meetings is often employed in the private sector to provide participants with souvenirs, Federal funds cannot be used for this purpose.

- CDC and ATSDR funds may be used for only those parts of the conference specifically supported by CDC or ATSDR as documented in the grant award.

- CDC and ATSDR will not fund 100% of any conference proposed under this announcement.

- CDC and ATSDR will not fund a conference after it has taken place.

### Background

CDC supports local, State, academic, national and international health efforts to prevent unnecessary disease, disability, and premature death, and to improve the quality of life. This support often takes the form of education, and the transfer of high quality research findings and public health strategies and practices through symposia, seminars and workshops. Through the support of conferences and meetings of important players in the areas of public health research, education, and prevention application, CDC is meeting its overall goal of dissemination and implementation of new cost effective intervention strategies.

ATSDR's systematic approaches are needed for linking applicable resources in public health with individuals and organizations involved in the practice of

applying such research. Mechanisms are also needed to shorten the time frame between the development of disease prevention and health promotion techniques and their practical application. ATSDR believes that conferences and similar meetings that permit individuals engaged in health research, education, and application (related to actual and/or potential human exposure to toxic substances) to interact are critical for the development and implementation of effective programs to prevent adverse health effects from hazardous substances.

### Purpose

The purpose of the CDC and ATSDR conference support grants is to provide PARTIAL support for specific non-Federal conferences in the areas of health promotion and disease prevention information/education programs (Except HIV Infection).

CDC applications are being solicited for conferences on:

- (1) Chronic disease prevention;
- (2) infectious disease prevention;
- (3) control of injury or disease associated with environmental, home, and workplace hazards;
- (4) environmental health;
- (5) occupational safety and health;
- (6) control of risk factors such as poor nutrition, smoking, lack of exercise, high blood pressure, and physical stress;
- (7) health education and promotion;
- (8) laboratory practices; and
- (9) efforts that would strengthen the public health system.

ATSDR applications are being solicited for conferences on: (1) Health effects of hazardous substances in the environment; (2) disease and toxic substance exposure registries; (3) hazardous substance removal and remediation; (4) emergency response to toxic and environmental disasters; (5) risk communication; (6) environmental disease surveillance; and (7) investigation and research on hazardous substances in the environment.

Because conference support by CDC and ATSDR creates the appearance of CDC and ATSDR co-sponsorship, there will be active participation by CDC and ATSDR in the development and approval of those portions of the agenda supported by CDC and ATSDR funds. In addition, CDC and ATSDR will reserve the right to approve or reject the content of the full agenda, press events, promotional materials (including press releases), speaker selection, and site selection. CDC and ATSDR funds will not be expended for non-approved portions of meetings. Contingency awards will be made allowing usage of only 10% of the total amount to be awarded until a final full agenda is

approved by CDC and ATSDR. This will provide funds for costs associated with preparation of the agenda. The remainder of funds will be released only upon approval of the final full agenda. CDC and ATSDR reserve the right to terminate co-sponsorship if they do not concur with the final agenda.

- Any conference sponsored by CDC or ATSDR shall be held in facilities that are fully accessible to the public as required by the Americans with Disabilities Act Accessibility Guidelines (ADAAG). Accessibility as per ADAAG also addresses accommodations for persons with sensory impairments.

- The conference organizer(s) may use CDC's name only in factual publicity for the conference, and should understand that CDC involvement in the conference does not necessarily indicate support for the organizer's general policies, activities, products or service.

Because CDC's and ATSDR's missions and programs relate to the promotion of health and the *prevention* of disease, disability, and premature death, only conferences focusing on such programmatic areas will be considered. Those topics concerned with health-care and health-service issues and areas *other than prevention* should be directed to other public health agencies.

#### Recipient Requirements

CDC and ATSDR grantees must meet the following requirements:

A. Manage all activities related to program content (e.g., objectives, topics, attendees, session design, workshops, special exhibits, speakers, fees, agenda composition, and printing). Many of these items may be developed in concert with assigned CDC and ATSDR project personnel.

B. Provide draft copies of the agenda and proposed ancillary activities to CDC and ATSDR for approval. Submit copy of final full agenda and proposed ancillary activities to CDC and ATSDR for approval.

C. Determine and manage all promotional activities (e.g., title, logo, announcements, mailers, press, etc.). CDC and ATSDR must review and approve any materials with reference to CDC and ATSDR involvement or support.

D. Manage all registration processes with participants, invitees, and registrants (e.g., travel, reservations, correspondence, conference materials and hand-outs, badges, registration procedures, etc.).

E. Plan, negotiate, and manage conference site arrangements, including all audio-visual needs.

F. Analyze data from conference activities that pertain to the impact on

prevention. Adequately assess increased knowledge, attitudes, and behaviors of the target attendees.

G. ATSDR grantees must develop and conduct education and training programs on prevention of health effects of hazardous substances.

H. ATSDR grantees must collaborate with ATSDR staff in reporting and disseminating results and relevant prevention education and training information to appropriate Federal, State, and local agencies, and the general public.

#### Technical Reporting Requirements

An original and two copies of the financial status and performance reports are due 90 days after the end of the budget/project period. The performance report should include: (1) Grant number; (2) title of the conference; (3) name of the principal investigator, program director, or coordinator; (4) name of the organization that conducted the conference; (5) a copy of the agenda; (6) a list of individuals who participated in the formally planned sessions of the meeting; and (7) a summarization of the results of the meeting, including a discussion of the accomplishments related to stated conference objectives.

With the prior approval of CDC and ATSDR, copies of proceedings or publications resulting from the conference may be substituted for the performance report, provided they contain the information requested in items (1) through (7) above.

#### Letter of Intent

Potential applicants must submit an original and two copies of a one-page typewritten Letter of Intent (LOI) that briefly describes the title, location, purpose, and date of the proposed conference and the intended audience (number and profession). The LOI must also include the estimated total cost of the conference and the percentage of the total cost (which must be less than 100%) being requested from CDC and ATSDR.

Requests for 100% funding will be considered non-responsive to this program announcement and returned to applicant without review. Current recipients of CDC and ATSDR funding must provide the award number and title of the funded programs. No attachments, booklets, or other documents accompanying the LOI will be considered. The one page limitation (inclusive of letterhead and signatures), must be observed or the Letter of Intent will be returned without review.

Letters of Intent will be reviewed by program staff for consistency with:

- CDC's mission of health promotion and disease prevention goals, agency priorities, and the purpose of this program; and

- ATSDR's mission to prevent exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment.

Following submission of a LOI, successful potential applicants will receive written notification to submit an application for funding. Applications may be accepted by CDC and ATSDR only after the LOI has been received by CDC and ATSDR and written invitation from CDC and ATSDR has been received by prospective applicant. An invitation to submit a final application will be made on the basis of the proposed conference's relationship to the CDC and ATSDR funding priorities and on the availability of funds.

#### Application Content

Applications may be submitted only after a Letter of Intent has been approved by the CDC and ATSDR and a written invitation from the CDC and ATSDR has been extended to the prospective applicant.

Invitation to submit an application does not constitute a commitment to fund the applicant. Applicants invited to apply must use application Form PHS 5161-1, and the following must be included:

A. *Two-Page Overview*—The overview must include the following:

1. Title of conference—include the term "conference," "symposium," "workshop," or similar designation to assist in the identification of the request;
2. Location of conference—city, State, and facility, if known;
3. Expected registration—target audience and number of persons expected to attend;
4. Date(s) of conference; and
5. Summary of conference objectives, format, and projected agenda, including a list of principal areas or topics to be addressed.

B. *Brief Background of Applicant Organization*—Include the organizational history and purpose, and previous experience related to the proposed conference topic.

C. *Narrative*—The narrative should cover the following:

1. A clear statement of the need for and purpose of the conference. This statement should also describe any problems the conference will address or seek to solve, and the action items or resolutions it may stimulate.

2. An elaboration on the conference objectives and target population. A *proposed agenda must be included*. A list of the principal areas or topics to be addressed, including speakers/facilitator, should be included. In addition, information should be provided about all other national, regional, and local conferences held on the same or similar subject during the last three years (if known).

3. A clear description of the evaluation plan and how it will assess the accomplishments of the conference objectives.

4. An operational plan or step-by-step schedule of major conference planning activities necessary to attain specified objectives. This schedule will include target dates by which the activities will be accomplished.

5. A description of any support (e.g., monetary, staff) or co-sponsorship related to this conference. (It is necessary that organizations seeking these grant funds be able to show additional support in the form of finances, services, etc., because this program provides Partial funding only.) For each organization contributing funding, a letter must be included documenting that support.

6. Any other information that will support this request for funds.

**Note:** Essential information requested in the Narrative should NOT be included as appendices to the application.

**D. Biographical Sketches—**Biographical sketches are needed for the individuals responsible for planning and implementing the conference. Experience and training related to conference planning and implementation as it relates to the proposed topic should be noted.

**E. Budget Information—**A total conference budget that includes the share requested from CDC as well as those funds from other sources (including income from the conference), and a justification consistent with the purpose, objectives, and operational plan of the conference. Also, identify the source(s) of the non-Federal share.

**F. Letters of Endorsement or Recommendations—**Letters of endorsement or recommendations supporting the organization and its capability to perform the proposed conference activity.

#### Evaluation Criteria

CDC and ATSDR applications will be reviewed and evaluated according to the following criteria (TOTAL 100 POINTS): (Please note the following: Section A.1., is ATSDR specific; only ATSDR applications will be reviewed and

evaluated using this criteria. Section A.2., is CDC specific. All other sections in these criteria are applicable to both CDC and ATSDR. Evaluation Criteria F. Budget Justification and Adequacy of Facilities, although not scored, contain a reference to funding information specific only to ATSDR applications.)

#### A. Proposed Program and Technical Approach (25 points)

Evaluation will be based on:

1. The public health significance of the proposed conference including the degree to which the conference can be expected to influence the prevention of exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases and other sources of pollution present in the environment. (Applicable to ATSDR applications only.)

2. The applicant's description of the proposed conference as it relates to specific non-Federal conferences in the areas of health promotion and disease prevention information/education programs (except HIV infection, mental health, and substance abuse), including the public health need of the proposed conference and the degree to which the conference can be expected to influence public health practices. Evaluation will be based also on the extent of the applicant's collaboration with other agencies serving the intended audience, including local health and education agencies concerned with health promotion and disease prevention. (Applicable to all CDC applications except ATSDR.)

3. The applicant's description of conference objectives in terms of quality and specificity and the feasibility of the conference based on the operational plan.

#### B. Applicant Capability (10 points)

Evaluation will be based on the adequacy of applicant's resources (additional sources of funding, organization's strengths, staff time, proposed facilities, etc.) available for conducting conference activities.

#### C. The Qualification of Program Personnel (20 points)

Evaluation will be based on the extent to which the application has described:

1. The qualifications, experience, and commitment of the principal staff person, and his/her ability to devote adequate time and effort to provide effective leadership.

2. The competence of associate staff persons, discussion leaders, speakers, and presenters to accomplish conference objectives.

3. The degree to which the application demonstrates knowledge of

nationwide and education efforts currently underway which may affect, and be affected by, the proposed conference.

#### D. Conference Objectives (25 points)

Evaluation will be based on:

1. The overall quality, reasonableness, feasibility, and logic of the designed conference objectives, including the overall work plan and timetable for accomplishment.

2. The likelihood of accomplishing conference objectives as they relate to disease prevention and health promotion goals, and the feasibility of the project in terms of the operational plan.

#### E. Evaluation Methods (20 points)

Evaluation will be based on the extent to which evaluation mechanisms for the conference will enable adequate assessment of increased knowledge, attitudes, and behaviors of the target attendees.

#### F. Budget Justification and Adequacy of Facilities (not scored)

The proposed budget will be evaluated on the basis of its reasonableness, concise and clear justification, and consistency with the intended use of grant funds. The application will also be reviewed as to the adequacy of existing and proposed facilities and resources for conducting conference activities.

The following is applicable for ATSDR applications only: Applications requesting funds in excess of \$10,000 may not be fully funded, depending upon availability of funds.

#### Executive Order 12372 Review

Applications are not subject to review as governed by Executive Order 12372.

#### Public Health System Reporting Requirements

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

#### Catalog of Federal Domestic Assistance

The CDC Catalog of Federal Domestic Assistance Number is 93.283. ATSDR's Catalog of Federal Domestic Assistance Number is 93.161.

#### Other Requirements

*Americans with Disabilities Act Accessibility Guidelines (ADAAG)*

All conferences sponsored by CDC or ATSDR shall be held in facilities that are fully accessible to the public as required by ADAAG. Accessibility under ADAAG addresses accommodations for persons with sensory impairments, as well as persons

with physical disabilities or mobility limitations. Prior to receiving an award, the applicant organization must assure compliance with the ADAAG.

### Submission Requirements and Deadlines

#### A. Letter of Intent (LOI)

1. *One Original and Two Copies* of the LOI must be postmarked by the following deadline dates in order to be considered in the application cycles. (FACSIMILES ARE NOT ACCEPTABLE.)

#### 2. Letter of Intent Due Dates:

October 6, 1997  
April 6, 1998

#### B. Application

1. *One Original and Two Copies* of the invited application must be submitted on PHS Form 5161-1 (OMB Number 0937-0189) and must be postmarked by the following deadline dates in order to be considered in the application cycles.

#### 2. Application Due Dates:

##### Earliest Possible Award Date:

January 12, 1998  
June 8, 1998  
March 1, 1998  
July 30, 1998

Applications may be accepted by CDC and ATSDR ONLY after the LOI has been reviewed by CDC and ATSDR and *written invitation* from CDC and ATSDR has been received by prospective applicant. An invitation to submit an application does not constitute a commitment to fund. Availability of funds may limit the number of Letters of Intent, regardless of merit, that receive an invitation to submit an application.

#### C. Addresses for Submission of Letters of Intent and Invited Applications

One original and two copies of the Letters of Intent and invited applications must be postmarked on or before the deadline date and mailed to: Henry S. Cassell, III, Grants Management Officer, Attention: Karen Reeves, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-09, Atlanta, GA 30305.

#### D. Deadline

Letters of Intent and Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or
2. Postmarked on or before the deadline date and received in time for submission to the independent review group. (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.)

#### E. Late Applications

Applications that do not meet the criteria in D.1. or D.2. above are considered late applications and will be returned to the applicant without review.

### Where To Obtain Additional Information

To receive additional written information, call (404) 332-4561. You will be asked to leave your name, address, telephone number and refer to Announcement Number 803. You will receive a complete program description, application form, and information on application procedures. CDC/ATSDR will not send applications by facsimile or express mail.

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

If you have any questions after reviewing the contents of all documents, you may contact: Karen Reeves, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-09, Atlanta, GA 30305. Telephone (404) 842-6596, E-Mail Address: [ker1@cdc.gov](mailto:ker1@cdc.gov).

Please refer to Announcement Number 803 when requesting information, submitting your Letter of Intent and submitting the invited application in response to the announcement.

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" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: April 23, 1997.

**Claire Broome,**

*Deputy Director, Centers for Disease Control and Prevention (CDC), and Deputy Administrator, Agency for Toxic Substances and Disease Registry (ATSDR).*

[FR Doc. 97-10967 Filed 4-28-97; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Statement of Organization, Functions, and Delegations of Authority

Part D (Food and Drug Administration), Chapter DA, Office of the Commissioner, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS) (35 FR 3685, February 25, 1970, and 60 FR 56605, November 9, 1995, as amended most recently in pertinent part at 54 FR 50536, December 7, 1989) is amended to reflect revised functions and title change for the former Executive Secretariat to the newly established Office of Executive Secretariat (OES), Office of the Commissioner, Food and Drug Administration (FDA).

The newly established OES will continue to serve as the focal point for the coordination, identification, development, and implementation of the agency's highest program priorities for the Commissioner. The OES staff will advise the Commissioner, Deputy Commissioners, Senior Staff members and other key agency officials on all activities that affect agencywide programs, projects and initiatives. This reorganization will simplify the organizational structure within the Office of the Commissioner. This action will further enhance and streamline the management and coordination of the agency's Executive Secretariat functions.

The proposed revisions are as follows:

1. Delete the *Office of Executive Operations (DAB)* under the Office of the Commissioner (DA), in its entirety and replace with the following:

*Office of Executive Secretariat (DAB).* Coordinates identification of and expedites development and implementation of the agency's highest program priorities and initiatives for the Commissioner.

Develops and maintains management information necessary for monitoring the Commissioner's and agency's goals and priorities.

Advises the Commissioner, Deputy Commissioners, Senior Staff members and other key agency officials on all activities that affect agencywide programs, projects, and initiatives. Informs appropriate agency staff of the decisions and assignments made by the Commissioner and Deputy Commissioners.

Assures that materials in support of recommendations presented for the