estimated copying costs of 5 cents per page and several conservative assumptions or estimates. Staff estimates that the ''average'' dispute-related file is about 25 pages long and that a typical annual audit file is about 200 pages in length. For purposes of estimating copying costs, staff assumes that every consumer complainant (or approximately 36,938 consumers) requests a copy of the file relating to his or her dispute. Staff also assumes that, for about 7,388 (20%) of the estimated 36,938 disputes each year, consumers request copies of warrantors' annual audit reports (although, based on requests for audit reports made directly to the FTC, the indications are that considerably fewer requests are actually made). Thus, the estimated total annual copying costs for average-sized files would be approximately $46,173 (25 pages/file × 36,938 requests) and $73,880 for copies of annual audits (200 pages/audit report × .05 × 7,388 requests), for total copying costs of $120,053, rounded to $120,000).

**John D. Graubert,**

*Acting General Counsel.*

[FR Doc. 01–20278 Filed 8–10–01; 8:45 am]

**BILLING CODE 6750–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Agency for Toxic Substances and Disease Registry

**[Program Announcement 02004]**

### Public Health Conference Support Grant Program; Notice of Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the availability of fiscal year (FY) 2002 funds for a grant program for Public Health Conference Support. This program addresses the health promotion and disease prevention objectives of ''Healthy People 2010''. This announcement is related to the focus areas of Arthritis, Osteoporosis, Chronic Back Conditions, Cancer, Diabetes, Disability and Secondary Conditions, Educational and Community-Based Programs, Environmental Health, Heart Disease and Stroke, Immunization and Infectious Diseases, Injury and Violence Prevention, Maternal, Infant and Child Health, Occupational Safety and Health, Oral Health, Physical Activity and Fitness, Public Health Infrastructure, Respiratory Diseases, Sexually Transmitted Diseases, and Tobacco Use. For a copy of ''Healthy People 2010'' visit the internet site http://www.health.gov/healthypeople

Conferences on Access to Quality Health Services, Family Planning, Food Safety, Health Communications, Medical Product Safety, Nutrition and Overweight, Substance Abuse, and Vision and Hearing, are not priority focus areas of CDC or ATSDR, and should be directed to other Federal Agencies. HIV is not included in this Program Announcement.

The purpose of conference support funding is to provide partial support for specific non-federal conferences (not a series) in the areas of health promotion and disease prevention information and education programs, and applied research.

Because conference support by CDC/ATSDR creates the appearance of CDC/ATSDR co-sponsorship, there will be active participation by CDC/ATSDR in the development and approval of the conference agenda. CDC/ATSDR funds will be expended only for approved portions of the conference.

The mission of CDC is to promote health and improve the quality of life by preventing and controlling disease, injury, and disability.

CDC supports local, Tribal, 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 (not a series) in the areas of public health research, education, prevention research in program and policy development in managed care and prevention application, CDC is meeting its overall goal of dissemination and implementation of new cost-effective intervention strategies.

ATSDR focus areas are: (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. The mission of ATSDR is to prevent both exposure and adverse human health effects that diminish the quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment.

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 (not a series) that permit individuals to engage in hazardous substances and environmental 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.

#### B. Eligible Applicants

Applications for CDC support may be submitted by public and private non-profit organizations. Public and private non-profit entities include State and local governments or their bona fide agents, voluntary associations, foundations, civic groups, scientific or professional associations, universities, and Federally-recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Only conferences planned for May 1, 2002 through September 30, 2003 are eligible to apply under this announcement.

**Note:** Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal Funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Applications for ATSDR support may be submitted by 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 Islands, 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.

Also eligible are nationally recognized associations of health professionals and other chartered organizations generally recognized as demonstrating a need for information to protect the public from the health effects of exposure to hazardous substances.

**C. Availability of Funds**

Approximately $1,100,000 may be available from CDC in FY 2002 to fund approximately 50 to 60 awards. It is expected that the average award will be $20,000. For FY 2002, awards will be made for three cycles (A, B, and C) each with a 12-month budget period within a 12-month project period. Funding estimates may change.

Approximately $50,000 is available from ATSDR in FY 2002 to fund approximately six awards. It is expected that the average award will be $8,000, ranging from $5,000 to $10,000. It is expected that the awards will begin on or about thirty days before the date of the conference and will be made for a 12-month budget period within a 12-month project period. Funding estimates may change.

**D. Use of Funds**

1. Funds may be used for direct cost expenditures: salaries; speaker fees (for services rendered); rental of necessary conference related equipment; registration fees; and transportation costs (not to exceed economy class fare) for non-Federal individuals.

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

3. Funds may not be used for the purchase of equipment; payments of honoraria (for conferring distinction); alterations or renovations; organizational dues; support entertainment or personal expenses; food or snack breaks; cost of travel and payment of a Federal employee; per diem or expenses for local participants (other than local mileage). Travel for federal employees will be supported by CDC/ATSDR. Travel for other Federal employees will be supported by the employees Federal agency.

4. Funds may not be used for reimbursement of indirect costs.

5. CDC and ATSDR will not fund 100 percent of any conference proposed under this announcement. Part of the cost of the proposed conference must be supported with other than Federal funds.

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

7. 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.

**E. Program Requirements**

Grantees must meet the following requirements:

1. The conference organizer(s) may use CDC's/ATSDR's name only in factual publicity for the conference. CDC/ATSDR involvement in the conference does not necessarily indicate support for the organizer's general policies, activities, or products or the content of speakers' presentations.

2. Any conference co-sponsored under this announcement shall be held in facilities that are fully accessible to the public as required by the Americans with Disabilities Act Accessibility Guidelines (ADAAG). Accessibility under ADAAG addresses accommodations for persons with sensory impairments as well as persons with physical disabilities or mobility limitations.

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

4. Provide draft copies of the agenda and proposed ancillary activities to CDC or ATSDR for approval. All but 10 percent of the total funds awarded for the proposed conference will be initially restricted pending approval of a full final agenda by CDC or ATSDR. The remaining 90 percent of funds will be released by letter to the grantee upon the approval of the final agenda. CDC and ATSDR reserves the right to terminate co-sponsorship at any time.

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

6. Manage all registration processes with participants, invitee, and registrants (e.g., travel, reservations, correspondence, conference materials and handouts, badges, registration procedures, etc.).

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

8. Analyze data from conference activities that pertain to the impact of prevention. Adequately assess increased knowledge, attitudes, and behaviors of the target audience.

**F. Application Content**

A letter of intent (LOI) is required for this Program Announcement.

Letter of Intent (LOI) instructions: Interested applicants are required to submit an original and two copies of a two to three-page in-depth typewritten Letter of Intent (LOI). Use English only and avoid jargon and unusual abbreviations. Upon review of the LOI's, CDC or ATSDR will extend written invitations to perspective applicants to submit applications. CDC or ATSDR will accept applications by invitation only. Availability of funds may limit the number of applicants, regardless of merit, that receive an invitation to submit applications. The LOI should specifically describe the following required information:

1. Justification of the conference, including the problems it intends to clarify and the developments it may stimulate;

2. Title of the proposed conference—include the term ''Conference,'' ''Symposium,'' ''Workshop,'' or similar designation;

3. Location of conference—city, state, and physical facilities required for the conduct of the meeting;

4. Expected registration—the intended audience, approximate number and profession of persons expected to attend;

5. Date(s) of conference—inclusive dates (not a series) of conference (LOIs without date of conference will be considered non-responsive to this program announcement and returned to the applicant without review);

6. Summary of conference format—projected agenda (including list of principal areas or topics to be addressed), including speakers or facilitator. 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; and also include on the first page:

a. The name of the organization.

b. Primary contact person's name.

c. Mailing address.

d. Telephone number.

e. And if available, fax number and e-mail address.

The LOI must include the estimated total cost of the conference and the percentage of the total cost (which must be less than 100 percent) being requested from CDC or ATSDR. Requests for 100 percent funding will be considered non-responsive to this program announcement and will be returned to the applicant without review. No Appendices, booklets, or other documents accompanying the LOI will be considered.

An invitation to submit an application will be made on the basis of the proposed conference's relationship, as outlined in the LOI, to the CDC or ATSDR funding priorities and availability of funds. LOIs should be provided by overnight mail service, or U.S. postal service.

The three-page limitation (inclusive of letterhead and signatures), must be observed or the letter of intent will be returned without review.

Application

Applicants may apply to CDC or ATSDR for conference support only after their LOI has been reviewed by CDC and ATSDR and a written invitation, including an application form, has been received by the prospective applicant.

An invitation to submit an application does not constitute a commitment on the part of CDC or ATSDR to fund the application.

In addition to the following required information, use the information in the Program Requirements and Evaluation Criteria sections to develop the application content:

1. A project summary cover sheet that includes:
(a) Name of organization.
(b) Name of conference.
(c) Location of conference.
(d) Date(s) of conference.
(e) Intended audience and number.
(f) Dollar amount requested.
(g) Total conference budget amount.

2. A brief background of the organization—include the organizational history, purpose, and previous experience related to the proposed conference topic.

3. 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.

4. An elaboration on the conference objectives and target audience. A list should be included of the principal areas or topics to be addressed. A proposed or final agenda must be included.

5. A clear description of the evaluation plan and how it will assess the accomplishments of the conference objectives. A sample of the evaluation instrument that will be used must be included and a step-by-step schedule and detailed operation plan of major conference planning activities necessary to attain specified objectives.

6. Biographical sketches are required 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.

7. Letters of endorsement or support—Letters of endorsement or support for the sponsoring organization and its capability to perform the proposed conference activity.

8. Budget plan and justification—A clearly justified budget narrative that is consistent with the purpose, objectives, and operation plan of the conference. This will consist of a budget that includes the share requested from this grant as well as those funds from other sources, including organizations, institutions, conference income and/or registration fees.

General Instructions: The narrative should be no more than 12 double-spaced pages, printed on one side, with one-inch margins, and 12-point font. Use English only and avoid jargon and unusual abbreviations. Pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and two required copies of the application must be submitted unstapled and unbound. Materials which should be part of the basic plan should not be in the appendices.

Send LOIs and Applications to: Edna M. Green, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146.

**G. Submission and Deadline for All Applicants**

Letter of Intent (LOI)

Letter of Intent Due Dates:

Cycle A: October 1, 2001, For conferences May 1, 2002–April 30, 2003

Cycle B: January 2, 2002, For conferences August 1, 2002–July 31, 2003

Cycle C: April 1, 2002, For conferences November 1, 2002–September 30, 2003

The letter of intent (LOI) must be submitted on or before October 1, 2001, January 2, 2002, and April 1, 2002. The applicant must submit an original and two signed copies of the LOI to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Applicants invited to apply should also submit the original and two copies of PHS form 5161–1, (OMB Number 0937–0189). Forms are in the application kit. Forms are also available at: http://forms.psc.gov/forms/PHS/PHS–5161–1.pdf

| Application due dates | Earliest possible award dates |
|---|---|
| CYCLE A: December 10, 2001. | April 1, 2002. |
| CYCLE B: March 8, 2002. | July 1, 2002. |
| CYCLE C: June 17, 2002. | September 30, 2002. |

Deadline: Filing deadlines have now been imposed for all conference support grants and dates should be strictly followed by applicants to ensure that there LOI's are received in a timely manner.

There will be three Conference Support reviews per year and awards will be made in the months of April 2002, July 2002, and September 2002.

If your Conference dates fall between Oct 1, 2001 to April 30, 2002, you should have applied under the previous program Announcement 01002 otherwise your LOI will be considered unresponsive to Cycle A under the 2002 Announcement.

If your Conference dates fall between May 1, 2002 to April 30, 2003, you can apply under Cycle A 2002.

If your Conference dates fall between August 1, 2002 to July 31, 2003, you can apply in Cycle B 2002.

If your Conference dates fall between November 1, 2002 to September 31, 2003, you can apply under Cycle C 2002.

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

1. Received on or before the date, or

2. Postmarked on or before the deadline date and received in time for orderly processing. (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 shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in 1. or 2. above are considered late applications, will not be considered, and will be returned to the applicant.

**H. Evaluation Criteria**

*Letter of Intent*

A conference is a symposium, seminar, workshop, or any other organized and formal meeting lasting portions of one or more days, where persons assemble to exchange information and views or explore or clarify a defined subject, problem, or

area of knowledge, whether or not a published report results from such meeting. The conference should support CDC or ATSDR's public health principles in furtherance of CDC's mission or ATSDR's mission. CDC will review the LOIs and compare conference objectives with our respective missions and funding priorities to determine if a full application will be invited. Less than 33 percent of LOI applicants are invited to submit full applications.

*Application*

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

Section 1.a., is ATSDR specific

Section 1.b., is CDC specific

Section 1.c., and all other sections in these criteria are applicable to both CDC and ATSDR

1. Proposed Program and Technical Approach (25 points).

a. 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).

b. 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 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 organizations serving the intended audience. (Applicable to all CDC applications except ATSDR)

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

2. Applicant's Capability (10 points).

Adequacy of applicant's resources (additional sources of funding, organization's strengths, staff time, proposed physical facilities, etc.) available for conducting conference activities.

3. The Qualification of Program Personnel (20 points).

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

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

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

c. The degree to which the applicant demonstrates the knowledge of nationwide and educational efforts currently underway which may affect, and be affected by, the proposed conference.

4. Conference Objectives (25 points).

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

b. 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.

5. Evaluation Methods (20 points).

Evaluation instrument(s) for the conference should adequately assess increased knowledge, attitudes, and behaviors of the target audience.

6. 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 or proposed facilities and resources for conducting conference activities.

**I. Other Requirements**

*Technical Reporting Requirements*

Provide the CDC with original plus two copies of:

1. a performance report, or in lieu of a performance report, proceedings of the conference, no later than 90 days after the end of the budget/project period.

2. financial status report, no later than 90 days after the end of the budget/project period.

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

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–7 Executive Order 12372 Review

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

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

AR–15 Proof of Non-Profit Status

AR–20 Conference Support

**J. Authority and Catalog of Federal Domestic Assistance Number**

The CDC program is authorized under Section 317 (k)(2) of the Public Health Service Act, [42 U.S.C. 241] as amended. The Catalog of Federal Domestic Assistance number is 93.283.

The ATSDR program is authorized under Sections 104(i)(14) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), [42 U.S.C. 9604(i)(14) and (15)]. The Catalog of Federal Domestic Assistance number is 93.161 for ATSDR.

**K. Where To Obtain Additional Information**

To receive additional written information, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. See also the CDC home page on the Internet: http://www.cdc.gov/od/pgo/funding/02004.htm

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Edna M. Green, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146, Telephone: (770) 488–2743, Email address: ecg4@cdc.gov

For program technical assistance, contact: C.E. Criss Crissman, Resource Analysis Specialist, Office of the Director Extramural Services Activity, Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, MS K–38, Atlanta, Georgia 30341–3714, Telephone: (770) 488–2513, Email address: cec1@cdc.gov

Dated: August 7, 2001.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 01–20221 Filed 8–10–01; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier: CMS–R–235]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Revision of a currently approved collection;

*Title of Information Collection:* Data Use Agreement and Information Collection Requirements, model language, and Supporting Regulations in 45 CFR, Section 5b;

*Form No.:* CMS–R–235 (OMB# 0938–0734);

*Use:* This agreement is used as a binding agreement stating conditions under which CMS will disclose and user will maintain CMS data that are protected by the Privacy Act.;

*Frequency:* On occasion;

*Affected Public:* Not-for-profit institutions;

*Number of Respondents:* 1,500;

*Total Annual Responses:* 1,500;

*Total Annual Hours:* 750.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access CMS's web site address at *http://www.hcfa.gov/regs/prdact95.htm*, or E-mail your request, including your address and phone number, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 17, 2001.

**John P. Burke III,**

*CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01–20226 Filed 8–10–01; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99D–4003]**

### Medical Devices; Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry.'' This guidance provides important preclinical, clinical, and labeling information that should be presented in an investigational device exemption (IDE), a premarket approval (PMA), or a product development protocol (PDP) application for any breast implant.

**DATES:** Submit written comments at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

**FOR FURTHER INFORMATION CONTACT:** Samie Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

This final guidance provides important preclinical (chemistry, toxicology, and mechanical), clinical, and labeling information that should be presented in an IDE, PMA, or PDP application. The information discussed is relevant to breast implants filled with silicone gel, saline, or alternative filler intended for breast augmentation, breast reconstruction, and revision.

This final guidance serves to update the information provided in the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' (64 FR 54028, October 5, 1999). FDA received two comments. The first comment requested FDA to strengthen the language used throughout the guidance. The second comment involved points to consider with regard to the device description, preclinical testing, and clinical sections of the guidance. This update is based on our additional scientific review and analysis of published studies, reviews of breast implant applications, the comments received, and discussions and correspondence between the Center for Devices and Radiological Health's Plastic and Reconstructive Surgery Devices Branch and breast implant sponsors. Although some minor updates were made in the chemistry and toxicological sections of the guidance, the primary revisions were to the mechanical testing and clinical data sections to reflect our current thinking on these topics. Additionally, FDA expanded the labeling section to address all essential pieces of labeling. The manufacturing section of the draft guidance was deleted because FDA concluded that it did not provide necessary information and, instead, wanted the guidance to focus on preclinical, clinical, and labeling issues.