APPLICANT ELIGIBILITY AND REQUIREMENTS: Eligibility for grant awards is limited to state agencies. Only one application per state will be accepted. Applicants must provide a letter from their state's Governor designating the applicant agency as the sole applicant for the state. Grantees are required to provide a 25% non-federal match during the first year, 35% during the second year, and 45% during the third year of the grant.

SUMMARY: The Administration on Aging announces that under this program announcement it will hold a competition for grant awards for fourteen (14) to twenty (20) projects that develop services and assistance, and improve the home and community based care system to better respond to the needs of persons with Alzheimer's disease, their families, and caregivers.

The deadline date for the submission of applications is April 21, 2000.

Application kits are available by writing to the Department of Health and Human Services, Administration on Aging, Immediate Office of the Assistant Secretary for Aging, 200 Independence Ave., SW, HHH Building, Room 309–F, Washington, DC 20201, or by calling 202/401–4547 or 202/401–4634.

Dated: February 14, 2000.

Jeanette C. Takamura,

Assistant Secretary for Aging.

[FR Doc. 00–3931 Filed 2–17–00; 8:45 am]

BILLING CODE 4154–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0001]

Leveraging—Collaborating With Stakeholders; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public meetings entitled ''Leveraging—Collaborating with Stakeholders.'' The purpose of these meetings is to discuss ways in which FDA can better leverage its expertise and resources by working with outside organizations. Participants may include, but are not limited to, academia, consumer groups, scientific experts, industry, public health providers, States, and other Government agencies.

DATES: The first meeting will be held on March 23, 2000. The second meeting will be held on April 12, 2000. For additional information regarding registration and the location and time of the meetings see table 1 in section III of this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov or to the Internet at http://www.fda.gov.

REGISTRATION AND REQUESTS FOR ORAL PRESENTATIONS: Send registration information (including name, title, firm name, address, telephone, fax number, and e-mail address) and requests to make oral presentations, to the appropriate contact person listed in table 1 of section III of this document by March 17, 2000, for the California meeting and by April 5, 2000, for the North Carolina meeting. Because space is limited, it is necessary to register in advance of the meetings and by the appropriate deadlines. Participants who wish to make a formal oral presentation should register with the appropriate contact for ''speaker registration'' identified by meeting in table 1 of section III of this document by the same deadlines listed above. Presentations will be limited to the questions and subject matter identified under section I of this document. All registration will be accepted on a first-come, first-served basis. Speakers will be chosen in order of registration. All other comments should be sent to the Dockets Management Branch (address above).

If you need special accommodations due to a disability, please indicate such at the time of registration.

You may register by e-mail, at http://www.fda.gov/oc/leveraging/stakeholders2000.

FOR GENERAL INFORMATION CONTACT: Virginia Cox, Office of the Commissioner (HF–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3409, FAX 301–594–6807, e-mail Vcox@oc.fda.gov. Local contact information is listed in table I of section III of this documnent.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is exploring new opportunities to leverage its own assets by working with other organizations in order to carry out its public health mission effectively in the 21st century. These collaborations are intended to have a larger net public health benefit to the American public than would be possible if FDA worked alone. The agency is currently working closely with a diverse set of partners, including public health organizations, scientific experts, other Federal regulators, States, industry and consumers, to expand these benefits. Leveraging activities are prominent in every major area of FDA responsibility, including:

(1) Safety related research,

(2) Safety review for new products,

(3) Monitoring safety of products on the market,

(4) Assuring industry compliance with safety regulations, and

(5) Patient/consumer education on the safe use of products.

The agency would like to expand these leveraging initiatives in order to address the increasingly complex regulatory challenges of this millennium.

In the section II. A. and B. of this document, FDA has provided illustrations of collaborative projects that are currently ongoing and those that are proposed. As you read through both sections, please respond to the following questions, as appropriate; these initiatives and questions will be discussed at the stakeholders meetings:

1. Does your organization share an interest in any of these initiatives?

2. If so, what role would your organization play in this initiative, and what could you contribute?

3. Do you have suggestions for improving FDA's approach to any of the leveraging initiatives?

4. Do you have suggestions for other organizations that would benefit from working with FDA on these types of efforts?

5. Are there other initiatives not listed below that you would suggest as a possibility for collaborative efforts between FDA and your organization or other organizations?

A. Examples of Ongoing Initiatives

1. Safety-Related Research—National Center for Food Safety and the Technology (Moffett Center)

The Moffett Center is a collaboration with industry, the Illinois Institute of Technology, and the University of Illinois' Food Science Department. The Moffett Center was established in 1987 to address food safety, specifically food processing and packaging technologies. The collaborative programs positioned the Moffett Center as a focal point of FDA's participation in research and technology outreach associated with the President's Food Safety Initiative focus on preventing and reducing foodborne contamination. The scope of food safety information and expertise achieved through this participation far outreaches the work any one member could accomplish to answer critical food safety questions. A recent expansion of

the Moffett Center focuses on small business needs in food safety. The Moffett Center research has helped in developing higher product safety standards and better consumer protection.

2. Safety Review for New Products—Product Quality Research Institute (PQRI)

PQRI fosters scientific research to support regulatory policy in the areas of drug substance, drug product, biopharmaceutics, science management, and novel approaches for regulating pharmaceuticals. PQRI provides opportunities to develop science-based publicly available information to: (1) Facilitate the drug development process, (2) facilitate needed changes in the manufacture of drug substance and drug product, (3) enhance review consistency and efficiency, and (4) increase reliance on tests that are no more burdensome than necessary to assure product quality. Co-sponsors include the Center for Drug Evaluation and Research (FDA), American Association of Pharmaceutical Scientists, Generic Pharmaceutical Industry Association, National Association of Pharmaceutical Manufacturers, Nonprescription Drug Manufacturers Association, National Pharmaceutical Alliance, Parenteral Drug Association, and Pharmaceutical Research and Manufacturers of America.

3. Assuring Industry Compliance With Safety Regulations—Mammography

Mammographies are provided by more than 10,000 facilities throughout the United States, a far greater number than FDA can effectively inspect for compliance with quality standards. The Mammography Quality Standards Act of 1992 (MQSA) requires these facilities to be accredited by FDA approved accrediting bodies that are either nonprofit organizations or State agencies and directs FDA to delegate site inspection tasks to States. FDA established mammography accreditation standards based on American College of Radiology (ACR) technical standards that are endorsed by other industry and government experts. FDA approved accreditation bodies now include ACR and several State agencies.

4. Patient/Consumer Education on the Safe Use of Products—Take Time to Care

The Take Time to Care Outreach program brings together FDA's Office of Women's Health and the National Association of Chain Drug Stores, and other senior citizen groups, professional associations, business/labor women's organizations and other health organizations. This network of organizations delivers the message about safe drug use, including the ''My Medicines'' brochure distributed at over 20,000 pharmacy outlets. Through this program, FDA expects to help 6.5 million women safely use their medications.

B. Examples of Proposed Initiatives

1. Safety Review for New Products—Safety Assurance in Clinical Trials

The volume of clinical trials has grown dramatically over the past decade, due to expanding development of new medical products. In addition, clinical trials are more often performed at multiple study sites, including multi-country studies. Extensive oversight by FDA is not feasible in an era of significantly scaled-back field staffing. FDA sees a growing need to collaborate with outside organizations in managing the research, compliance and educational aspects of clinical investigations, particularly those sponsored by academia, industry, other government agencies and other private institutions/corporations.

2. Assuring Industry Compliance with Safety Regulations—Gene therapy, Human Cellular and Tissue Based Products

Advances in these categories of new medical products create the need for better science to assure product safety and strategies to assure industry compliance with safe manufacturing practices. FDA is interested in exploring collaborative strategies for research studies that will lead to the development of scientifically based standards for: Safety and toxicity of viral vectors carrying a human gene for replacement or reconstitution; safety of cell substrates for use in production of live-attenuated viral vaccines or gene therapy vectors; and quality control and safety of human cellular and tissue-based products.

3. Patient/Consumer Education on the Safe Use of Products—Risk Management

FDA is interested in launching widespread educational initiatives, aimed at consumers, of newly approved medical products, as well as important products that have been on the market. The agency would like to target, in particular, vulnerable populations such as children, the elderly and those with special needs. FDA would also like to capitalize on the capabilities of the Internet to get its message to the right people. It would be very useful to join forces with other organizations in order to amplify and focus messages that would help consumers/patients better manage their own health status.

4. Inspections—Internet

The Internet is being used by a rapidly growing number of consumers to obtain information about drugs and to order these medical products. FDA is in the early stages of an initiative to monitor firms marketing drugs through this medium. The agency is interested in exploring ways to collaborate with other organizations in order to extend its ability to monitor the situation and to keep consumers safe and informed.

5. Safety-Related Research—NCTR Identified Opportunity

Work on gene-chip and gene-array technology to provide high-throughput screening of biomarkers for susceptible populations is already underway. This is being done in collaboration with academia, industry and government. However, we see a growing need to collaborate in the development of DNA microarray technology to better define biomarkers of toxic response that are more relevant and applicable to the human population. The FDA is interested in exploring strategies with its stakeholders to develop the capacity to utilize these DNA-, RNA-, and bioinformatic-based technologies to better understand toxin-induced responses in in vitro and in vivo model systems to improve extrapolation of these systems to the human.

II. Comments

Stakeholders are encouraged to submit their responses in advance of the March 23, 2000, and April 12, 2000, meetings. Written comments should be identified with docket number 00N–0001 and submitted to the Dockets Management Branch (address above).

III. Scheduled Meetings

TABLE I.

Date and Location	Address	Scheduled Time	Attendance and Speaker Registration
March 23, 2000, Stanford, CA.	Stanford Law School, rm. 290, 559 Nathan Abbott Way, Stanford, CA.	6 p.m. to 8 p.m. PST.	Judy Keast, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 118ON, Oakland, CA 94612, 510–637–3960, ext. 112, FAX: 510–637–3976, e-mail: Jkeast@ora.fda.gov.
April 12, 2000, Durham, NC.	Duke University Medical Center, Searle Conference Center, Seeley Mudd Bldg., Research Dr., Durham, NC.	1 p.m. to 3 p.m. EST.	Mary Lewis, Food And Drug Administration, 310 New Bern Ave., rm. 370, Raleigh, NC 27601, 919–856–4456, FAX: 919–856–4776, e-mail: Mlewis@ora.fda.gov.

IV. Transcripts

Transcripts of the meetings (from each site listed in section III of this document) may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: February 11, 2000,

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–3840 Filed 2–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–310]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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: New Collection.

Title of Information Collection: Health Care Services for Deaf and Hard of Hearing Adults—Case Story Forms.

Form No.: HCFA–R–310 (OMB #0938–NEW).

Use: The Agency seeks to obtain beneficiary information that helps providers: (1) Better understand situations in which problems may be avoided when encountering a hearing-impaired or deaf individual; (2) explore how such encounters may affect the delivery of quality care of adversely impact health care outcomes; and (3) provide an opportunity for hearing-impaired individuals to develop more appropriate health-seeking behavior, where indicated. This form is to be used by deaf and hard of hearing individuals accessing the Delmarva web site who may wish to identify experiences receiving health care in the United States. The experiences may be either good or bad. Respondents are asked to complete a form for each case or experience.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 100.

Total Annual Responses: 100.

Total Annual Hours: 17.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Dated: February 8, 2000.

John P. Burke III,

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

[FR Doc. 00–3948 Filed 2–17–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Announcement of Office of Management and Budget (OMB) Control Numbers for Agency Information Collections Approved Under the Paperwork Reduction Act of 1995

AGENCY: Health Care Financing Administration, HHS.

This notice announces and displays OMB control numbers for Health Care Financing Administration (HCFA) information collections that have been approved by OMB.

Under OMB's regulations implementing the Paperwork Reduction Act (PRA), 44 U.S.C. 3501, each agency that proposes to collect information must submit its proposal for OMB review and approval in accordance with 5 CFR part 1320. Once OMB has approved an agency's proposed collection of information and issues a control number, the agency must display the control number.

OMB regulations provide for alternative methods of displaying OMB control numbers. In the case of collections of information published in regulations, display is to be ''provided in a manner that is reasonably