

# FOOD AND DRUG ADMINISTRATION

## Introduction

Public confidence is warranted in FDA by ensuring industry's compliance with Federal laws regulating products in commerce. The Food and Drug Administration (FDA) is a regulatory agency with primary responsibilities for assuring the safety and efficacy of foods, drugs, biologics, cosmetics, medical devices, and radiological products. The FDA accomplishes its mission through enforcement of the Food, Drug and Cosmetic Act (the Act) and subsequent regulations. The Act authorizes pre market review and post market surveillance of products, and the provision of education and information programs.

The following plan highlights objectives of ongoing and planned activities and to increase the involvement of Asian and Pacific Islanders in Agency programs. The FDA plans to collaborate with other Department of Health and Human Services' operating and staff divisions to initiate a variety of programs and activities to support the Asian and Pacific Islander Initiative (API).

The FDA administers a program that provides opportunities for all groups to participate/compete in its procurement activities. The FDA will improve communications through the Internet connections with the Small Business Administration (SBA) and other Federal agencies. All expenditures are subject to the availability of funds. Opportunities for participation in extramural initiatives will be announced in the Commerce Business Daily and the Federal Register. The FDA uses a variety of personnel and procurement authorities, interagency and cooperative agreements.

## Implementation Infrastructure

The FDA established its intra-Agency Coordinating Committee for coordination of minority initiatives. Its offices are headquartered in Rockville, Maryland, with field installations in six regions including field operations in all 50 states and Puerto Rico. The FDA consists of headquarters' administrative policy offices and six centers. Each policy office and the six centers have a Minority Initiatives contact.

The FDA uses the Committee to support other Departmental initiatives such as the Hispanic Agenda for Action, the Tribal Colleges and Universities Initiative, and the Asian Pacific Islander Initiative. On an as needed basis the core Committee membership is expanded to include the proper representation.

FDA designated Minority Liaison serves on the Departmental Minority Initiatives Coordinating Committee, the Work Group on Tribal Colleges and Universities, the Work Group on Asian and Pacific Islanders.

FDA's Minority Health Liaison is the alternate to the Deputy Commissioner for External Affairs on the HBCU Steering Committee. FDA's Minority Health Liaison supports the Hispanic Agenda for Action Steering Committee members.

## Framework

## **I. ACCESS TO AND UTILIZATION OF HEALTH AND HUMAN SERVICES**

Goal 1.Improve health and well being of AAPIs by increasing their access to and utilization of health and human services.

a. Key Activity: Mammography

Continue distribution of Things to Know About Quality Mammograms.

Lead Entity: Laurel Eu, M.A. Public Affairs Specialist, Los Angeles District Office, U.S. Food and Drug Administration and the FDA's Office of Women's Health in partnership with various Asian and Pacific Islander community centers and clinics in California.

The purpose of the project was to translate a brochure developed and focused tested by the Agency for Health Care Policy Research (AHCPR). AHCPR translated the brochure into Chinese, Korean, Laotian, Vietnamese, Tagalog. FDA coordinated translations of the brochure into Cambodian, Samoan, and Thai per intramural funding from FDA's Office of Women's Health. The brochure was designed to explain what occurs during the mammography procedure, and assist the women in preparing for this exam. Questions to ask the technician and how to follow up with results were included in the brochure.

A clinician's recommendation packet was developed and translated into seven languages (plus English)by FDA. The packet provided a mechanism for clinicians to personally recommend that women make and keep their appointments for mammography and breast/pap smear/pelvic exams. Key phone numbers could be supplied by the clinician.

Time frame: Development: 1996, Distribution and reprinting: 1996 to present.

Measurable Outcome: Distributed at Asian Pacific Health Fairs and Clinics in Southern California, California Breast and Cervical Cancer Program partners, National Asian Women's Health Organization, American Medical Women's Association, Southeast Asian Communities in Dallas, Houston, Portland, Missouri, Chicago, and an army post in Korea. The brochures have received very positive reactions from the communities. Requests were numerous. This is one of the few pamphlets dedicated to the procedures themselves. Physicians report high client appeal. Patients read brochure before procedure (or clinician can use it as a guide to explain;) patients express being more comfortable with procedure.

b Key Activity: Pap Smear

Continue to distribute brochure Things to Know About Getting A Pap Smear

Lead Entity: Laurel Eu, MA, Public Affairs Specialist, U.S. Food and Drug Administration and the FDA's Office of Women's Health in partnership with various community agencies.

The purpose of the project was to develop and translate a brochure in Chinese, Korean, Vietnamese, Thai, Samoan, Cambodian, Laotian and English. The brochure emphasized the importance of getting a pap smear, how to interact with clinicians and follow up with obtaining results. This

brochure sought to present the Pap test procedure in an honest, sensitive manner on what to expect, how to prepare for the procedure, including practical concerns such as how to dress appropriately and make appointments. The clinician recommendation packet (described in the Breast Cancer-mammography project) is used in conjunction with this brochure. Brochure produced with intramural funding from FDA's Office of Women's Health.

Time frame: Developed in 1996. Reprinting and distribution in 1997-1998.

Measurable Outcome: There is an ongoing demand for the materials. The State Breast and Cervical Cancer Prevention Project use our materials for their Asian Pacific partners. The materials are used by the organizations listed in mammography project mentioned earlier, plus others including Medical Centers in Minneapolis, Chicago, Oregon, and New York, and Southern California sites including Southeast Asian Health Clinic, Asian Health Care Venture, and T.H.E. Clinic. Comments: Patients do not have a problem with the procedure after going through the brochures. Clinicians like the packets and brochures and can select material from the brochure if the client does not want to read the entire brochure. This year, two medical residents from Glendale Medical Center will be working with FDA to assist in outreach and education to the Chinese community.

c. Key Activity: Nutrition Labeling Education for Asian and Pacific Islanders

Lead Entity: Laurel Eu, M.A., Public Affairs Specialist, U.S. FDA, Los Angeles District Office in partnership with various community agencies.

The project was designed to make nutritional labeling education available to APIAs who were linguistically isolated or had limited English proficiency API audiences. Three booklets for each language were produced. Read the Label (based on low literacy booklet), Nutrients on the Food Label and Links to Health based on the FDA-American Heart Association (AHA) brochure How to Read the New Food Label. Languages were Chinese, Korean, Vietnamese, Thai, Laotian, and Cambodian. Graphics showing typical Asian foods were included. An educational packet was produced for health educators. Project funded through intramural funding from FDA Office of Public Affairs (OPA).

Time frame: 1994 to present.

Measurable Outcome: Each language was made available for three booklets (How to Read the New Food Label, Nutrients on the New Food Label and, Links to Health). The community was very receptive. Previously, APIAs often complained that their products did not include the new nutrition label; now many more products have the new label. APIA community nutrition education programs have used the materials. Materials gaining renewed interest in Anemia Task Force in Orange County, California.

d. Key Activity: Internet

Developed a web site containing the translated breast and cervical cancer screening and food label materials. Website is hosted on an APIA targeted communication server named *APANet*. *APANet* develops and promotes the use of multi-media and communication technologies relevant to the needs and perspectives of the Asian Pacific Islander communities. FDA's APIA site <http://www.apanet.org/~fdala>. Funding provided by FDA's Office of Women's Health.

Lead Entity: Laurel Eu, M.A., Public Affairs Specialist, FDA Los Angeles District Office, in partnership with *APANet*.

Time frame: Ongoing.

Measurable Outcome: The translated materials on cervical and breast cancer screening have been more widely distributed to API communities via this website coordinated by *APANet*, which has the communication infrastructure that can maximize APIA outreach electronically. *APANet*, was developed UCLA and four well-established Asian and Pacific community organizations — a community-based communications infrastructure that utilizes electronic technology. The *APANet* coalition now includes more than 30 partners. The partnership goals are to provide training, linkages, consumer education and information access for Asian Pacific Islanders, especially low income, disadvantaged immigrant youth and adults. This broad-based *APANet* coalition has developed and promoted the use of electronic technology for their API clients, and provided training on how to use this technology on site and via community computer learning centers. The website has enabled community agencies and clinicians to communicate with the FDA District Office, and to download any of the materials needed. The response has been very positive, and the coordinator has been able to assist API clients with referrals and information.

e. Key Activity: Safe Use of Medications — A brochure translated in Cambodian, Vietnamese, and Chinese.

Lead Entity: Laurel Eu, M.A., Public Affairs Specialist, Los Angeles District Office, U.S. Food and Drug Administration.

Time frame: 1994 to present.

Measurable Outcome: The purpose of this project was to promote medication safety to the API communities by encouraging the basics of reading labels, understanding and following instructions, talking to a doctor and/or pharmacist, and to accurately and completely describe medication history. Very good reception, but distribution limited. Coordinator would like to update booklet or use translated materials from the Take Time to Care program which is being prepared for national roll out.

f. Key Activity: Women's Health: Take Time to Care — TTTC

Lead Entity: Marsha Henderson, FDA Office of Women's Health (OWH), working with representatives from various district offices.

The purpose of this project was to help women take better care of their health. The program is designed to reach women over 45, particularly those who are under served. OWH worked with a broad network of partners to shape TTTC, including government agencies and elected officials, national health and consumer organizations, women's groups, health care providers and health institutions.

Time frame: TTTC was piloted in Hartford, Connecticut, and Chicago, Illinois in the spring of 1997. These efforts have been assessed and the necessary adjustments have been made in preparation for the national roll out of TTTC, which will begin in March 1998 and will continue throughout the year

in the selected cities and rural locations throughout the country.

Measurable Outcome: The program component of reducing the misuse of medications within this audience has been piloted, focused tested, and will be distributed nationally soon. The program has been well received by participants. API translations are being explored.

g. Key Activity: Internet consumer education on Food Safety for Asian Pacific Islanders

Lead Entity: Laurel Eu, M.A., Public Affairs Specialist, Los Angeles District Office, U.S. Food and Drug Administration.

Time frame: To be determined.

Measurable Outcome: To be determined. It is important to include minority populations, (including Asian Pacific Islanders) in the President's Food Safety Initiative announced recently. Food borne illness statistics and emerging pathogens are a growing concern. Different populations have dietary practices that may place them at increased risk for Food borne illnesses. An important objective would be to decrease risk of food borne illnesses among APIs by promoting healthier food handling practices and consumption choices. Data needs to be collected, and educational materials and programs that address APIA needs should be produced. As a first activity, placing press releases on the APAnet website would be explored.

h. Key Activity: Tobacco

Final rule for regulating tobacco became effective in August 1997. Since then the FDA has worked to increase compliance with tobacco regulations and to ensure that those industries directly affected by it understand why the government chose this action and what their responsibilities are under the rule.

Lead Entity: Sharon Natanblut, Associate Commissioner for Special Initiatives

Time frame: Ongoing

Measurable Outcome: Worked with major organizations representing retailers to hold regional conferences.

Worked with the print and electronic media, and public health journals to encourage public service announcements and articles.

Developed and Distribute materials to inform retailers of their responsibilities.

Developed consumer information materials in Chinese, Korean, and Vietnamese to explain the tobacco regulations. Posted these materials on the Internet.

Established and maintained a toll-free hotline.

Participated in and exhibited at major conferences and meetings with community organizations, parent groups, voluntary health groups, and others who can help raise awareness of the tobacco rule and encourage compliance.

## **II. ASIAN AMERICAN AND PACIFIC ISLANDER DATA**

Goal 2: Increase and improve collection, analyses, and dissemination of data about AAPI populations and subpopulations.

The FDA is a member of the HHS Data Council. The Council has recommended the inclusion of race and ethnicity information in all HHS sponsored data collection activities, using the OMB definitions for race/ethnicity reporting. The Data Council's Working Group on Race and Ethnicity has been asked to review strategies to collect race and ethnic data and to make recommendations on overall strategy.

## **III. RESEARCH ON ASIAN AMERICAN AND PACIFIC ISLANDER HEALTH**

GOAL 3: Increase the number of funded research projects and programs targeted towards APIs.

a. Key Activity: Women's Health Intramural Grants

FDA's Office of Women's Health is dedicated to the stimulation and support of original research and outreach programs by that show promise for contributing to an understanding of women's health. Intramural projects include a wide range of research and outreach projects: Women in Clinical Trials, Gender Differences, Coronary Heart Disease, Pregnancy, Sexually Transmitted Diseases, Mammography Quality Standards Act, Breast Implants, Autoimmune Diseases, Osteoporosis, Foods and Cosmetics.

## **IV. TRAINING**

GOAL 4: Increase outreach to and participation of APIs in HHS or HHS sponsored training programs

- a. Expand Federal Equal Opportunity Recruitment Program (FEORP) to include targeting of all Senior Executive Service positions.
- b. Implement a Minority Faculty Fellows Program to identify and select faculties from institutions of higher education for temporary employment at the FDA during summer vacations and sabbaticals.
- c. Utilize the Service Fellowship Program for attracting scientists.
- d. Enlarge its reservoir of qualified medical, scientific, engineering, journalism, and health professionals through the minority recruitment programs such as internships, fellowships, minority recruitment, personnel exchanges (scientific and professional), Cooperative Education (CO-OP), Commissioned Officer Student Training and Extern Program (COSTEP), and the summer employment program, Stay-in-School Programs, and the Minority Access Research Careers Program (MARC)-- coordinated through the National Institutes of Health.

Key Activity: Internships, Externships, and Summer Hires

Lead Entity: Various district offices have internship and summer hire programs that may include API students. For example, in the Los Angeles District Office, API students from the University of California have served as interns on the health communication project.

Measurable Outcome: In 1997, the Office of Special Health Issues involved two API students in the Pharmacy Externship Program.

- e. Publicize fellowships, internship and other training and recruitment. Consult with API government professional organizations such as the Asian American Government Executives Network to: (1) identify barriers to API outreach and recruitment; (2) develop outreach and recruitment activities to increase the pool of APIs considered for positions in FDA; and, (3) identify outreach and recruitment efforts to increase API representation in key positions such as regional office staff that work most directly with API communities.

- f. Key Activity: Oncology Patient Training Residency Program

Lead Entity: Center for Drug Evaluation and Research and the Office of Special Health Issues

After meeting with representatives of the Cancer advocacy community in November of 1996, the Division of Oncology Drug Product in CDER in partnership with the Office of Special Health Issues has designed a pilot Oncology Residency Program. The goal of the program is twofold: to educate cancer survivors/advocates about FDA's drug review and approval process and then through the cancer survivor to educate the cancer community about the process.

Four pilot residents have been selected from candidates recommended by the cancer community. One resident has completed the program and three are at various stages in the program. Residents begin the program by attending a one-week seminar which FDA scientific reviewers attend. After attending, each resident will attend two to four training sessions in the Division of Oncology Drug Products. Each training session is three to five days in length. During a training session, a resident will receive one on one orientation from the Division's Special Assistant and individual review scientists. The resident will also attend all division drug review meetings during the training session. At the completion of the program each resident will write a reaction paper about the Residency Program. Each Resident will also through speeches, workshops and articles educate their cancer community about their experience. Residents are brought on board as Special Government Employees (SGE) who must adhere to the confidentiality laws that cover all government employees. As SGEs, the Residents are acting in a consulting capacity to FDA and are salaried and compensated for travel and living expenses.

## **V. WORKFORCE AND PARTICIPATION IN HHS OPERATIONS**

Goal 5. Ensure that issues affecting under served API populations are addressed through representation in the FDA work force and participation in FDA operations.

- a. Key Activity: Diversity Data Bank.

The FDA recognizes the benefits of having a diverse workforce and views it as an integral part of accomplishing its mission. FDA has established a Diversity Data Bank designed to assist managers throughout the agency in identifying qualified candidates to fill vacancies wherever they occur. This system will enhance diversity at all levels, in all occupations, and in all career opportunities. This includes, but is not limited to, the Minority Faculty Fellows Exchange Program, advisory boards, committees, panels, and employment.

b. Key Activity: Leadership Program.

The FDA implements a Leadership Program. The purpose of the program is to develop high-potential GS-14-15 employees for future leadership positions in the Agency. The program targets women and other minorities, including Asian and Pacific Islander employees for development. Each participant develops a individual development program with the assistance of a mentor.

c. Key Activity: Recruitment and Outreach

Enlist FDA employees in the mission oriented occupations to participate in Career Days and employment fairs targeting graduating seniors;

Bring students to FDA laboratories for educational tours on experiments and research;

Encourage FDA personnel to volunteer as mentors, tutors, classroom speakers, workshop leaders, and hosts.

Increase the participation of Asian and Pacific Islanders, particularly faculty on FDA panels, advisory committees, and science boards.

d. Key Activity: Advisory Committees

Use 41 technical advisory committees which review complex scientific data and make recommendations to the Agency on the safety, effectiveness, and labeling of drugs, medical devices, food and food safety, biological and blood products, veterinary products and radiation safety standards. Consumer representatives provide the Agency with the consumer perspective on many policy and health issues that affect the public.

Work with a Consortium of consumer organizations to recruit and assess candidates to serve as consumer representatives on the FDA's advisory committees. The Consortium was established in 1979 and consists of members of consumer organizations representing national, state, and local interests, diversely geographical locations; and a wide range of constituencies, including older individuals, minorities, and women. The primary responsibility of the Consortium is to assist the FDA with the recruitment, interviewing, and assessment of candidates to serve as consumer representatives on FDA advisory committees.

## **VI. CROSS CUTTING COLLABORATION TO ENHANCE HHS CUSTOMER SERVICETO AAPIS**

GOAL VI: Enhance HHS capacity to serve Asian American and Pacific Islander customers.

The Food and Drug Administration will work to improve customer satisfaction. To accomplish this FDA will operate based on specific guiding principles: (1) be responsive to all FDA constituencies to assure optimum levels of customer satisfaction; (2) be knowledgeable of FDA policies and programs; (3) be sensitive to our responsibilities toward national and global consumer communities; (4) assure accuracy and timely responses to consumers' requests for service and information; (5) inform

and educate consumers about the safe and effective use of the FDA regulated products and self-help protection concepts, and (6) foster and facilitate constructive opportunities for participation in Agency decision making.

The FDA strives to inform and educate consumers about the FDA's policies and programs and the relative impact on public's health. Public participation is important to assuring a balance in policy making. FDA facilitates dialogue with diverse constituents by implementing a wide range of public participation, information, and outreach services and coalition building initiatives. The FDA informs its constituencies about the safety and effectiveness of the FDA regulated products through materials and initiatives which are designed to emphasize Agency policy and to address consumer health concerns.

a. Key Activity: National Consumer Forums

The Food and Drug Administration convenes national and local forums with consumers and community-based organizations. The Forum provides opportunities for the Food and Drug Administration's decision makers to dialogue with a broad spectrum of consumer leaders and organizations on an array of regulatory and consumer-oriented issues. The purpose of the Forums is to foster discussions of health and policy issues important to FDA or to consumers. The Forum is critical to establishing a middle ground for promoting constructive dialogue and inclusion of consumers in FDA initiatives. From these Forums, the Agency can better determine areas of public support for, or conflict with, Agency policy. We can also identify grassroots issues and concerns at these meetings.

Lead Entity: Office of Consumer Affairs

Measurable Outcome: The anticipated results are improved understanding and communication, if not agreement, between FDA and the public, and a greater balance in FDA's decision making process.