# Chapter 8 – Outreach and Leveraging

## Contents

# Introduction

The 21st century has presented the U.S. Food and Drug Administration (FDA) and the Office of Regulatory Affairs (ORA), FDA's inspectional and enforcement arm, with unprecedented challenges. A few of these include the pace of scientific and technological development, the rate and quantity of data under review, the increasing complexity of distribution chains, and the greater sophistication of products and mimicry by counterfeiters. To accomplish its mission of promoting and protecting the public health, the Agency needs to be innovative, resourceful, and forward looking to ensure that it will meet its mission in the years ahead. To ensure steady focused progress, the FDA has created blueprints that map out the critical challenges facing the Agency, to facilitate the development of effective strategies to ensure protection of the public health.

Through specially targeted initiatives, the FDA is intensifying efforts to ensure the safety of America's food supply, and to make safe, effective, and affordable medical products available to the public.

During the late summer of 2007, ORA embarked on a revitalization of its operations in response to the dynamic environment and the challenges presented by a changing world. A change in our approach and infrastructure is necessary. The logistical realities confronting ORA require an evaluation of the regulated industry, of its workforce, and of its tools to ensure that ORA has the necessary resources to meet its mission in light of today's and tomorrow's reality. Since ORA's force of dedicated employees play a pivotal role on the front line of protecting public health, they need to have the resources and tools necessary to perform their jobs efficiently and effectively.

As is often the case, these challenges have led to opportunities to strengthen and enhance ORA. The Food Protection Plan (FPP or the Plan), and the Action Plan for Import Safety[1], provide frameworks for building future public health protections and approaches in which ORA is a vital and active leader. In addition, the Food and Drug Amendments Act of 2007 (FDAAA) significantly expands FDA's authority in areas that will have a substantial impact on ORA's activities and its mission. These initiatives and legislation significantly influence the capability of ORA to develop even greater capacity for meeting its current and future challenges.

[1] The Action Plan for Import Safety is also known as the Import Safety Action Plan (ISAP)

ORA staff members are spread across the country, providing a valuable force of dedicated, diverse, and highly qualified employees who share a common vision of ensuring that *all food is safe; all medical products are safe and effective; and the public health is advanced and protected*. The revitalization effort expanded upon this common vision in developing a strategic frame that ultimately became a key driver of the ORA Revitalization Strategy. The mission statement for the Revitalization states:

> *ORA is an integral and vital part of FDA. We are a highly skilled, unified workforce dedicated to protecting and promoting public health. This is accomplished by continuously improving and utilizing all available tools and resources, and working collaboratively with our partners to protect the public from unsafe and ineffective FDA regulated products of foreign or domestic origin. Risk to public health is reduced, and regulatory compliance is maximized along the entire product lifecycle from origin to domestic use.*[2]

The Revitalization Strategy supports the mission statement ORA previously developed to guide its work: "*ORA protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products.*" ORA is not alone in this effort and must partner with FDA's product Centers, the Office of the Commissioner, and other federal, state, local, and foreign regulatory authorities to provide the greatest protection for the public health.

## FDA Protects the Public

The FDA is proactive in assuring the safety and effectiveness of products marketed in the United States through ensuring the safety, purity, potency, and effectiveness of biological products including vaccines, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury as well as the safety and effectiveness of medical devices and the safety of radiological products used by the public. FDA assures that the food and the food ingredients that imports and exports are safe. FDA also oversees animal food additives, drugs and animal devices that relieve animal pain and suffering, sustain their health, and improve animal productivity ensuring these products are safe and protect the public health.

[2] Margaret O'K. Gavin, Associate Commissioner for Regulatory Affairs, *Report to the Commissioner*, January 2008.

**The Food Protection Plan**

The FDA has developed a comprehensive plan to address changes in food sources, production, and consumption. The globalization of the food supply, new threats and communication issues, require a new approach to food protection. Through specially targeted initiatives, FDA has intensified its efforts to address food safety and food defense through prevention, intervention, and response focused initiatives.

FDA developed an Agency-wide, visionary strategy for food protection as a comprehensive, integrated, national foods system for FDA regulated food of both domestic and foreign origin. Through objectives defined in the Plan, FDA has ensured the communication of Agency-wide food protection policies and program decisions to food safety partners, including federal, state, and international agencies. FDA has conducted outreach with federal, state, local, and international agencies, academic and non-profit organizations, professional and trade associations, industry, and the public to communicate FDA food safety and defense issues. FDA has taken action and promoted initiatives to create a climate for cooperative work relations amongst food safety partners and started building an infrastructure to support FDA's food protection program objectives.

Since the release of the FPP, the FDA has worked collaboratively across the Agency to address the three core elements of the Plan: prevention, intervention, and response. Selected objectives and domestic accomplishments achieved in FY08 include:[3]

**Prevention:**

- Promoting Increased Corporate Responsibility to Prevent Foodborne Illness:
    - A 50-state meeting was held August 12 through 14, 2008, in St. Louis, Missouri, to share information and develop implementation strategies between FDA, other federal, state, and local partners for the FPP, the ISAP, and the FDAAA.
    - FDA has issued Federal Register Notices announcing a docket requesting "stakeholders comments on the implementation of the FPP "as a part of a broad outreach plan. Docket number FDA-2008-N-0188, "Food Protection Plan."
- Identify Food Vulnerabilities and Assess Risk:

[3] Action Plan for Import Safety, FDA Activities (November 2007 – June 2008).

- FDA has developed an assay to assess the stability of two bioterrorism agents in high-risk foods. This assay can be used to assess other chemicals that may be used by terrorists to contaminate the food supply.

- Developing Risk-Based Processes:

  - FDA's ORA, the Center for Food Safety and Applied Nutrition (CFSAN), and the Food Field Committee have collaborated to develop and use a risk-based framework to create a FY08 work plan for the ORA field force.

- Expand the Understanding and Use of Effective Mitigation Measures:

  - FDA is using genetic analysis to identify hundreds of *Salmonella* strains from seafood imports. The analysis provides information that can be used to trace outbreaks of *Salmonella* and implement surveillance programs to ensure food safety.

**Intervention:**

- Focus Inspection and Sampling Based on Risk:

  - FDA has increased inspection efforts of low acid canned food (LACF) facilities to ensure that manufacturers are adhering to applicable FDA requirements, thereby ensuring the public is protected from pathogens such as *Clostridium botulinum*.

  - ORA has completed a 3-year plan for increasing the number of state inspections, enhancing inspectional coverage of firms.

- Improve the Detection of Food System "Signals" that Indicate Contamination:

  - FDA is developing new methods for rapidly and accurately identifying contaminants in food, improving our ability to detect harmful chemicals such as melamine.

  - FDA microbiologists have received training at CDC's *Salmonella* Reference Laboratory on a new molecular method for rapidly and accurately identifying *Salmonella* serovars. The instrumentation needed for these methods has been purchased by both CFSAN and ORA laboratories, enhancing their ability to detect these pathogens in foods.

  - FDA has developed a method for detecting mycotoxins in distillers' grains improving our ability to limit exposure in foods.

**Response:**

- Collaborating with States on Response Efforts:
    - FDA has developed an additional Farm Investigation Course for federal, state, and international investigators. Training for states was held in February 2008.
- Improve Risk Communications to the Public, Industry, and Other Stakeholders:
    - FDA has developed templates for recall communications and presented them to the FDA Risk Communication Advisory Committee for input in March 2008. This improves communication and provides better information on recalled products to the public allowing better product identification by consumers.

## Collaborating to Ensure Food Safety

The possibility of public health emergencies arising in the U.S. could impact many people in the wake of recent food contaminations, hurricanes, tsunamis, acts of terrorism, and the threat of pandemic influenza. FDA's collaborative work with other federal agencies is long-standing and enables FDA to better conduct many of its day-to-day enforcement activities. More importantly, these collaborative relationships enable immediate responses in emergency situations resulting in increased protection of the public health. The best example of this is during an outbreak of foodborne illness. This section provides just a few examples of the many interactions with other federal and state agencies that occur day-to-day.

### The Food Emergency Response Network (FERN)

In coordination with the U.S. Department of Agriculture (USDA), ORA established the Food Emergency Response Network (FERN), a nationwide network of federal, state, and local laboratories capable of microbiological, chemical, and radiological testing of food commodities. Speed in identifying whether food is contaminated is critical to reducing the risk of death and illness resulting from human exposure, and such collaborative efforts are vital to ORA's future success. Currently, 138 laboratories representing 50 states and Puerto Rico have satisfactorily completed the FERN Laboratory Qualification Checklist, which provides the FERN National Program Office (NPO) with vital information to determine if a laboratory meets the criteria for participation. To enhance their capacity and capabilities, 13 of these chemical and radiological laboratories receive funding and other support from FDA. The USDA also funds microbiological laboratories.

- FERN plays a number of critical roles related to food security and food defense. These include:

    - Prevention. FERN provides a national surveillance program that will offer early means of detecting threat agents in the American food supply;

    - Preparedness. FERN establishes an infrastructure that prepares the nation's laboratories to be able to respond to food-related emergencies;

    - Response. FERN offers significant surge capacity that will strengthen the nation's response towards widespread complex emergencies, whether they are intentional or inadvertently related to agents in food; and

    - Recovery. The FERN network of laboratories enhances the ability of the country to restore confidence in the food supply following a threat or an actual emergency targeted at the nation's food supply.

For FY08, FERN has been involved with:

- Special Event Food Defense Assignment (SEFDA)

    - The SEFDA is the latest food defense related FDA field activity. State SEFDA was designed as a proactive effort to prepare for the protection of food that would be served during the Republican and Democratic National Conventions, as well as to develop a template for future special security events. It was planned and conducted jointly with several FDA operational divisions including: CFSAN, ORA, FERN Laboratories, and state and local regulatory agencies in Minnesota and Colorado (the sites for the 2008 National Political Conventions). SEFDA activities continued until May 23, 2008.

- Protein Surveillance Assignment (PSA)

    - In June 2008, a report was released about the PSA field activity, conducted in May and June of 2007. The PSA is one of several food defense related FDA field activities. This was the first food defense related FDA field activity that concurrently looked at both the food and feed supply. The activity was planned and conducted jointly with several FDA components including; ORA, CFSAN, CVM, and FERN Laboratories.

- Food Defense Surveillance Assignment (FDSA)

    - The FDSA was the first food defense field assignment that engaged several federal, state and local organization representatives in all aspects of the

planning, implementation and evaluation of this activity. The assignment tested communication and coordination between regulatory agencies when examining a dual jurisdictional commodity. It was conducted jointly with several FDA and USDA components and included many state and local regulatory agencies as well as FERN Laboratories. The assignment was designed around a finished product regulated by both the FDA and the USDA and is commonly used in the National School Lunch Program.

## Outreach and Leveraging via FDA Centers

### Center for Biologics Evaluation and Research

The Center for Biologics Evaluation and Research (CBER) regulates allergen testing products in addition to blood, vaccines, tissues, and medical devices related to licensed blood and cellular products. They also regulate human gene therapy products and xenotransplantation.

CBER's Office of Blood Research and Review (OBRR) participated in an American Association of Blood Banks (AABB) meeting in Montréal, Québec, Canada, from October 4 to 7, 2008. The four day meeting included scientific sessions on transfusion medicine and blood banking, panel discussions, and presentation of scientific abstracts.

On October 6, 2008, OBRR staff participated in an "Ask the FDA and Health Canada" session which addressed questions submitted by AABB membership. Health Canada participated in the 90 minute question and answer session for the first time. Panelists addressed nearly 40 questions from blood establishments and transfusion services on issues ranging from product manufacturing to patient care, regulations in the Code of Federal Regulations to recommendations in guidance documents.

OBRR research was prominently displayed at the scientific poster presentations at AABB. The abstracts presented were published in a supplemental edition of the journal *Transfusion*.

### Center of Devices and Radiological Health

The Center of Devices and Radiological Health (CDRH) is comprised of multiple offices that utilize a broad range of activities to ensure the safety of regulated products while promoting new product development. The Office of Compliance (OC) and the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) protect the public

health by enforcing regulations and laws to which the regulated industry is subject, without hindering innovation or access to medical devices and radiological health products.

CDRH has launched an Electronic Communication Initiative to provide more efficient and effective methods of communicating with industry, health care professionals, device user facilities, and the public.

CDRH has a Medical Device Postmarket Transformation Initiative to increase its ability to identify, analyze, and act on postmarket information to improve the safety and effectiveness of medical devices and radiation-emitting products.

## Center for Drug Evaluation and Research

The Center for Drug Evaluation and Research (CDER) is responsible for evaluating new drugs before they can be sold to consumers to ensure the drugs are safe and effective for use. CDER has oversight responsibilities for prescriptions, over-the-counter, and generic drugs, and ensures that both brand name and generic drugs, work correctly, and that the health benefits outweigh known risks to consumers.

CDER oversees the research, development, manufacture, and marketing of drugs. It is responsible for truth-in-advertising for prescription drugs, and monitoring the use of marketed drugs for unexpected health risks.

### *Unapproved Drug Initiative*

In an effort to improve patient safety and better inform consumers, in September 2008, the Center for Drug Evaluation and Research (CDER) through the Division of New Drugs and Labeling Compliance in OC launched a new, improved Website to provide industry, health care professionals, and consumers information about the risks of unapproved drugs. The Website provides valuable information regarding enforcement priorities aimed at efficiently and rationally bringing all such drugs into the approval process.

For more information on CDER's unapproved drug initiative see:
http://www.fda.gov/cder/drug/unapproved_drugs/default.htm

In collaboration with FDA's television studios, the CDER's OC Division of New Drugs and Labeling Compliance developed a Video News Release (available on the unapproved drugs Website) aimed at educating health care professionals and

consumers about marketed unapproved drugs, the associated safety risks of these products, and the FDA's efforts to bring these products into compliance.

*FDA's Efforts to Better Educate Industry Professionals Industry Outreach Initiative*

The CDER's OC has developed and implemented an outreach initiative to increase the transparency of regulatory requirements and surveillance programs to the pharmaceutical industry. Presentations to non-profit industry groups are an opportunity for industry personnel to stay informed on evolving Center requirements and policy, and provide FDA program staff the opportunity to be updated on industry practices.

FDA subject matter experts give presentations on regulatory requirements for submission of safety, administrative data, compliance with manufacturing, and clinical trial operations. Presentations have been given at large general pharmaceutical industry meetings, and at subject focused workshops which provide industry an opportunity to raise general questions during question and answer sessions, as well as discuss company specific issues informally during breaks and at exhibit displays.

This outreach program has served to stimulate industry to voluntarily modify procedures and performance, and communicate industry best practices, without requiring the use of field inspectional resources. The program offers efficient and cost-effective measures to manage the risk associated with non-compliance through communication with industry on joint activities to increase the safety of products used by American consumers, while expanding our knowledge of industry operations.

*Shifting from Paper to eSystems*

Recent legislation requires that the FDA's drug registration and listing program to shift to an all electronic system called "eDRLS." The CDER OC Division of Compliance Risk Management and Surveillance designed an outreach program that promotes eDRLS through an exhibit display and presentation program that provides information regarding the system to potential registrants and product listers. The display is educational, demonstrating the system's features.

Informational and promotional literature outline the features of the new system and encouraged industry's participation in the system's pilot program. Attention was focused on eDRLS draft guidance that provides user information and effectively ends the paper system on May 31, 2009. FDA expects the electronic system to foster industry compliance through ease of use, elimination of redundancy, and validation of data entry.

*Confirming Bioanalytical Assay Reproducibility*

CDER OC Division of Scientific Investigations (DSI) addressed a significant problem in bioequivalence data reproducibility identified in the FDA inspection program. Several inspections, conducted by DSI as part of FDA's Bioresearch Monitoring (BIMO) Program, found that validated bioanalytical methods on some occasions failed to demonstrate acceptable reproducibility when samples were reanalyzed. DSI conveyed the scientific merits of this concern to industry at various meetings and workshops, and the need to assure a proper evaluation of sample reproducibility for bioequivalence, pharmacokinetic, and toxicokinetic studies used in FDA review decisions.

Consequently, bioanalytical laboratories are implementing procedures to evaluate reproducibility, including follow-up investigations if non-reproducibility is found. DSI continues to address this significant issue that impacts data integrity through the bioequivalence inspection program.

**Center for Food Safety and Applied Nutrition**

The FDA's Center for Food Safety and Applied Nutrition (CFSAN) has protected the health of Americans by assuring the safety of food, food additives, dietary supplements, infant formula, and cosmetics. CFSAN works to prevent intentional and unintentional contamination of food, deploys screening technologies to identify microbial and chemical contamination, and responds quickly to contain outbreaks of foodborne illness.

While the goals of FDA are to first prevent contamination of fresh produce, risks to consumers can be greatly minimized by prompt, and effect recall actions. The Los Angeles District personnel participated in the United Fresh Produce Association workshop, "Training for a Recall, Communicating Under Fire," held in Phoenix, Arizona, and Los Angeles, California, during FY08. The workshop was a hands-on instructional two-day course to help fresh produce companies reduce public health risks and minimize the incidence of foodborne illness associated with consumption of contaminated fresh produce through effective traceability and recall programs. This Los Angeles District outreach initiative was intended to improve response and minimize the risk of illness associated with consumption of fresh produce. The outreach assisted the fresh produce industry in gaining knowledge needed to implement a product recall and develop a crisis plan. The course gave fresh produce companies opportunities to hear from legal professionals, communication experts, FDA staff, and industry leaders. The goal was to ensure everyone within the affected company's recall team knows how to work together effectively and efficiently in the event of a product recall situation.

CFSAN promoted September as National Food Safety Education Month. The educational Website contained materials for children, pregnant women and specific audiences including Asian American, American Indians, and Alaskan Natives. The articles are in English and Spanish. In addition to CFSAN, the information was presented by USDA, Centers for Disease Control and Prevention (CDC), and Partnership for Food Safety Education.

## Center for Veterinary Medicine

The Center for Veterinary Medicine (CVM) is an internationally recognized public health organization responsible for evaluation, approval, and surveillance of animal drugs, food additives, feed ingredients, and animal devices.

### *Food From Animal Clones*

On January 15, 2008, FDA issued documents on the safety of food from animal clones. After years of detailed study and analysis, the FDA concluded that meat and milk from clones of cattle, swine, and goats, and the offspring of clones from any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals. There was insufficient information for the Agency to reach a conclusion on the safety of food from clones of other animal species, such as sheep.

### *Food Safety Initiatives*

CVM participates in the various food safety initiatives by:

- Developing and coordinating the National Antimicrobial Resistance Monitoring System, a collaboration between FDA, USDA, and the CDC, that identifies drug resistant profiles in foodborne pathogens isolated from meat, poultry and other foods;

- Funding cooperative agreements to study the microbiological hazards associated with the food animal production environment, which includes animal feeds; and

- Supporting educational initiatives focused on prudent and judicious drug use practices.

## ORA and the Government Wide Quality Assurance Program

Since 1975 FDA's ORA, as recommended by the Government Accountability Office (GAO), and directed by the Office of Management and Budget (OMB), maintains information on the Current Good Manufacturing Practice (CGMP) status of drugs, some biologics, and device firms.

This information is made available to the Veterans Administration (VA), the Department of Defense (DOD), and other domestic and foreign government agencies that procure medical supplies through the Government Wide-Quality Assurance Program (GQWAP) for use in award decision making. This information ensures that federal agencies and our veterans and military personnel receive medical supplies that are produced in conformance with CGMP. The VA uses this information in its maintenance of the Federal Supply Schedule, the medical product component of the Government Supply Administration, which lists acceptable medical products for purchase by government agencies. This program also provides critical information for the issuance of FDA device and drug export certificates.

Currently, a Web-based, redacted version of the database, which is updated daily, is shared with state officials having a signed Memorandum of Understanding with the FDA. This system is known as "COMSTAT" (Compliance Status Information System), and users of the system are able to view a firm's manufacturing compliance profile status, as well as the date of last completed QS or CGMP inspection. There are seven states and eleven countries that have access to the database. In FY08, the GQWAP provided a total 1,388 assessments to the VA, and DOD, supported a Website for external viewers, and conducted quality assurance monitoring assessments.

## Other Partnerships

### Centers for Disease Control and Prevention

The FDA has a strong, long-standing, collaborative working relationship with the Centers for Disease Control and Prevention (CDC). Although FDA has the lead responsibility within the Department of Health and Human Services (HHS) for ensuring the safety of food products, the CDC has an important complementary and non-regulatory public health role. CDC is the lead Federal agency for conducting disease surveillance and outbreak investigations in collaboration with the States and routinely monitors the occurrence of specific illnesses in the U.S. that may be attributable to contaminated foods within the food supply.

CDC input during traceback investigations often helps with identification of the causes and sources of outbreaks of foodborne illnesses.

Some areas of collaboration include:

- FDA joined with CDC and the World Health Organization (WHO) in issuing a statement about infant formula contamination with melamine amid news reports.

- In 2008, CDC worked with state, local and tribal health departments, the Indian Health Service, and FDA to identify the source of a large outbreak of *Salmonella* Saintpaul. Comprehensive tracebacks of produce sampling and investigation ultimately led to the identification of jalapeño and Serrano peppers as sources of contamination.

**FDA Outreach and Partnerships with the States**

FDA partners with the States to protect the public health in many areas. However, there are four major areas where FDA places special reliance upon the States to conduct inspections: mammography, retail food protection, milk safety, and shellfish sanitation. FDA provides training and guidance to assist the States in conducting inspections, sometimes under contract with FDA. In addition, FDA provides regulatory guidance and expertise to the states. The Public Health Service Act directs FDA to "assist states ... in the prevention of communicable diseases" and to advise states "on matters relating to preservation and improvement of the public health."

In addition, FDA through CFSAN has funded grassroots food safety, food defense, and nutrition education projects to be conducted around the country by FDA Public Affairs Specialists. A large number of the projects target underserved populations, while others are aimed at susceptible populations including pregnant women and seniors. A majority of the projects target culturally diverse populations. Many projects focus on nutrition education to enhance consumers' ability to make healthy dietary choices.

*State and Federal Contract and Partnership in Inspection Programs*

Inspections are performed in selected food, drug, biologics and device manufacturing or food processing facilities to determine compliance with the Act, state law, or both. FDA's work involves conducting foreign and domestic premarket and postmarket inspections, investigations, and laboratory analyses. Premarket activities include bioresearch monitoring of clinical research, preapproval inspections, laboratory method validations to support premarket application decisions, and inspections of

manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in its application.

The largest portion of work involves postmarket inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers. FDA also monitors, examines and samples imported products in each of these critical areas to ensure they meet the same rigorous safety and effectiveness standards as domestic FDA regulated products.

For more information on state inspection contracts go to:
www.fda.gov/ora/partnership_agreements/Contracts/default.htm

*Feed / BSE Inspection Contract Program*

The Medicated Feeds Program was implemented with the assistance of the states under contract since 1973. For the last several years, states assisted ORA and have accomplished many surveillance inspections to determine whether firms manufacturing medicated feeds are in compliance with key CGMP regulations. The "Second Generation Medicated Feed Regulation," published by the FDA in 1986, set forth revised requirements concerning approval procedures for the manufacture of animal feeds containing new animal drugs. FDA is required to inspect these firms once every 2 years.

On June 5, 1997, FDA published a final rule prohibiting the use of mammalian protein in ruminant feeds. This action was taken to prevent the spread of bovine spongiform encephalopathy (BSE) in the U.S. There are currently 35 contracts with the states. Three hundred fifty four (354) inspections were accomplished via contracts for Feed Mill CGMPs and 4,684 for BSE.

*Tissue Residue Inspection Contract Program*

Under this program, the FDA inspections of producers/owners are conducted after identification of a tissue residue violation by U.S. Department of Agriculture's Food Safety and Inspection Service. The primary objectives of the inspection are to determine and document the cause of the violative tissue residue. The inspection obtains information on the producer's/owner's operations, drug usage, animal husbandry practices, feed delivery systems, responsibility for the violation, and disposition of any remaining animals. This program keeps our food supply safe by maintaining watchful vigilance over violative producers.

*Food Inspection Contract Program*

Under this program, inspections are performed of selected food manufacturers/processors to determine compliance with the Federal Food, Drug and Cosmetic Act, state law, or both. The major inspectional emphasis is placed upon determining significant CGMP violations. These may include the identification of insanitary conditions and practices that may render the food injurious to health, particularly those involving the introduction of pathogenic organisms, and other conditions that may have caused food to become filthy, putrid, decomposed, or contaminated. Eighteen states have contracts with the FDA. Under this program a total of 635 inspections have been accomplished since its inception.

*MQSA Inspection Contract Program*

The Mammography Quality Standards Act (MQSA) of 1992 was signed into law on October 27, 1992. The intent of the Act is to ensure that women receive high quality mammography for early breast cancer detection by requiring the establishment of a federal certification and inspection program for mammography facilities. The Act authorizes FDA to obtain state and local assistance in enforcing the MQSA requirements including annual inspections of all certified mammography facilities. Currently 47 states participate in the MQSA program accomplishing 7,950 inspections.

*National Milk Drug Residue Database*

The FDA and the states share responsibility for assuring that the nation's milk supply is safe and not contaminated with harmful residues of drugs. This task is accomplished through a cooperative agreement between FDA and the States under the National Conference on Interstate Milk Shipments (NCIMS).

The National Milk Drug Residue Database was implemented in cooperation with the National Conference on Interstate Milk shipments, an organization of state officials responsible for the Grade A fluid milk production in this country. The contract is part of an ongoing effort to improve control over drug residues in the milk supply and to demonstrate the amount and results of collective industry and government milk testing.

**Federal-State Liaisons**

The Division of Federal-State Relations (DFSR) participates in cooperative and educational efforts designed to inform industry, health professionals, and the public

about FDA's functions and its commitment to safeguard the public health. DFSR interacts with, and serves as the focal point for, cooperating state and local officials and associations of these state officials, in order to promote cohesive and uniform policies and activities in food and drug-related matters.

For many years FDA has entered into partnerships with the states to conducting joint inspections and educational training for inspectors. These partnerships may be self-renewing, open duration, or on-going partnerships. FDA also has partnerships with other entities to ensure communication of information and regulatory requirements that help to protect the public health.

The following is a partial list of activities resulting from state partnerships:

- Collecting off-shore clam and ocean quahog samples and analysis for harmful biotoxins.

- Collecting and analyzing fresh fruit, vegetables and other food products for harmful pesticides and industrial chemical contaminants.

- Sampling and analyzing raised or processed fish and fish food for illegal drugs, pesticide, industrial chemical residues and determining if artificial colors, heavy metals, or illegal drugs are present in fish feeds.

- Conducting compliance testing of new assemblies or re-assemblies of x-ray equipment.

- Training on HACCP for state inspectors.

- Educating consumers about the risks and dangers of AIDS fraud.

- Coordinating the food protection efforts by reducing consumer risk, eliminating duplication of effort, defining regulatory roles in all non-retail food establishments excluding meat, poultry, and dairy operations.

- Training program for acidified foods for state inspectors.

- Work sharing, data sharing, and educational exchanges, including all current and future inspectional and sampling contracts to enhance consumer protection in the area of food safety.

- Training activities to promote health and scientific education.

- Inspectional coverage of over-the-counter drug manufacturers and repackagers.

- Sharing oversight and authority of regulated dairy manufacturing facilities.

To see a comprehensive list of partnership agreements go to:
http://www.fda.gov/ora/partnership_agreements/Current/default.htm

**Association Partnerships**

The FDA, the National Association of Boards of Pharmacy and the Federation of State Medical Boards of the U.S., Inc., agreed to establish a partnerships to share information and work cooperatively to enforce federal and state laws and regulations relating to illegal domestic prescribing and dispensing of prescription drugs on the internet.

**Private Industry**

The Small Business Program Office is designed to help small businesses participate in the Agency's procurement and contract activities. FDA has representatives who exclusively help small businesses whose products are regulated by FDA. These individuals can provide information that clarifies how Agency laws and regulations apply to specific circumstances and suggest methods of meeting those requirements.