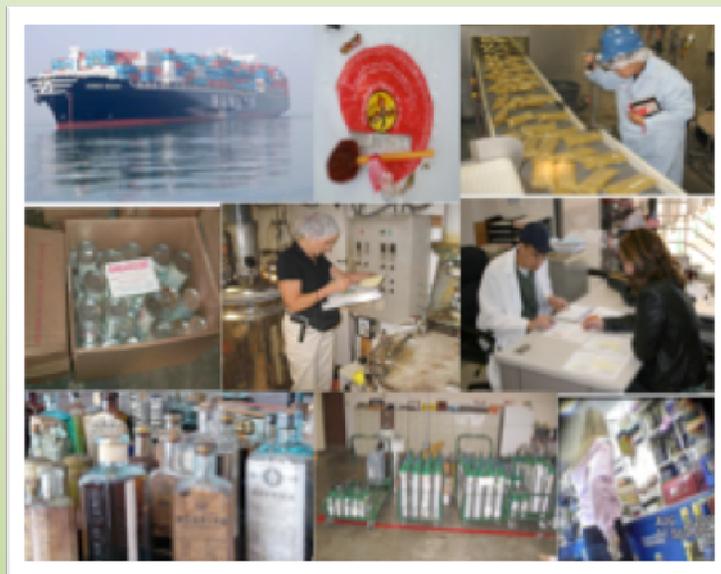


# California Food and Drug Branch

2010 Strategic Plan

April 30, 2010



California Department of  
**Public Health**



# California Food & Drug 2010 Strategic Plan

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# Message From the Branch Management Team

On behalf of the Branch and our Strategic Planning Team, we are delighted to share with you the first California Food & Drug Branch Strategic Plan, since the creation of our new department, The California Department of Public Health. The Food & Drug Branch is committed to the safety of foods, drugs, medical devices, cosmetics and consumer products used or consumed by the citizens of California and our vision and goals for the future support that mission.

As the Food and Drug Branch looks forward to the future, we recognize the need to pause and reflect on how our directions and priorities throughout the past have been shaped by the needs of the industries we regulate and by the needs and expectations of citizens across California. During this period of fiscal crisis and expanding responsibilities, FDB never lost sight of its public health mission.

There is much less certainty from year to year as both General Fund support and licensing/registration revenues fluctuate. Program responsiveness, an essential element of our mission, is no longer automatic--it becomes a difficult choice among programs and activities. Societal needs and expectations, technological advances, demographic and economic change--all indicated an opportune time for FDB to take stock, assess its current position and strengths and build for the future, while keeping in sight its public health mission and the tradition of state service which has served FDB and California so well. In this process of creating our future, we as a public health law enforcement community came together once again--to reaffirm an institutional mission and to foster an attitude of collaboration and shared responsibility in achieving that mission.

Staff from across all levels and programs of our Branch volunteered to work as members of this cross-functional planning team to bring the Food & Drug Branch Strategic Plan to life. Their input added both depth and the daily realities of their jobs to our deliberations and built upon the foundational core established in the Department's Strategic Plan and the Division of Food, Drug and Radiation Safety Primary Initiatives. The plan is the product of their work and has had the broadest possible review across the Branch.

The FDB Vision, Mission, Goals, and Objectives reflect bold steps toward continuously improving the safety of the California food and drug marketplace and demonstrating our consumer protection leadership role. Our values statement reflects the ways in which we expect to work together as a branch, and with our stakeholders, as we partner on behalf of all California consumers.

Since we consider strategic planning more of a process than a product, this is only the beginning of this process for the Food & Drug Branch. The plan will be a living document that is reevaluated and monitored continuously, and revised as needed. Your ideas and input are invited and welcomed at any time.

The FDB management team is deeply appreciative of the help of all who participated in creating this plan.

Sincerely,

Ingeborg Small  
Patrick Kennelly  
Michael Ayala



## California Department of Public Health Strategic Plan for 2008 - 2010

### 10 Public Health Essential Services

1. **Monitor** health status to identify community health problems.
2. **Diagnose** and investigate health problems and health hazards in the community.
3. **Inform, educate, and empower** people about health issues.
4. **Mobilize community partnerships** to identify and solve health problems.
5. **Develop** policies and plans that support individual and community health efforts.
6. **Enforce** laws and regulations that protect health and ensure safety.
7. **Link** people to needed personal health services and assure the provision of health care when otherwise unavailable.
8. **Assure** a competent public health and personal healthcare workforce.
9. **Evaluate** effectiveness, accessibility, and quality of personal and population based health services.
10. **Research** for new insights and innovative solutions to health problems.

## **Division of Food, Drug and Radiation Safety Food and Drug Branch Primary Initiatives**

Improving Communications: Because we recognize and need to make the most of the extraordinary knowledge, energy, and commitment of the Food and Drug Branch staff, we commit to foster a professional culture of openness and information sharing, both internally and externally.

Ensuring Staff Success: Employees are our most valued assets. We must work in a positive environment where excellence is expected, cultivated, acknowledged, rewarded, and celebrated. We must foster a culture of trust, respect, and mutual support among all staff and managers.

Strengthening Partnerships: Strengthening partnerships is a fundamental principle to increase effectiveness of public health organizations. We commit to create new personal and professional partnerships and continue to build upon our existing relationships to increase trust, credibility, and co-commitment--and ultimately, we will be much more successful to achieve our public health goals and provide better public service.

Improving Documentation and Transparency: Improving our program activity documentation will provide us with opportunity to highlight staff's excellent public health contributions and identify trends that will help to adjust our programs to anticipate and better respond to emerging issues. At the same time, it means that we are more openly accountable and subject to questioning.

# Food and Drug Branch



The Food and Drug Branch (FDB) is one of California's oldest consumer protection agencies. It is a part of the Department of Public Health, Center for Environmental Health, Division of Food, Drug and Radiation Safety. California's founders, during the first California legislative session in 1850, passed laws making it illegal to sell adulterated food. The overall objective

of the branch is the protection of the public from illness, injury, and death from exposure to unsafe foods, drugs (prescription and over-the-counter), medical devices, cosmetics and consumer products. The objectives of the program are met through licensing, certification, inspection, education, and enforcement activities.

FDB licenses, inspects, and regulates:

- Food manufacturers
- Canneries
- Bottled water manufacturers
- Water vending machines
- Retail water treatment facilities
- Private water source operators
- Water haulers
- Shellfish handlers
- Medical device manufacturers
- Drug manufacturers and
- Home medical device retailers



To prevent inadequate operations from beginning business, FDB must inspect firms before they become licensed. When necessary, enforcement actions are taken to prevent the distribution of contaminated foods, drugs, and medical devices. The program is also responsible for investigating foodborne outbreaks, drug tampering, and recalls of contaminated foods.



## Protecting California's Food Supply Through Effective Inspections, Emergency Response and Food Industry Education



The Food Safety Section employs 85 staff consisting of Peace Officer investigators and doctoral level scientists. The section licenses 15,800 operations including processed food



manufacturers or distributors, canneries, water bottlers, private water sources, water haulers, retail water facilities, water vending machines, bottled water distributors, shellfish handlers, organic food processors or handlers, cold storage facilities, frozen food facilities and olive oil manufacturers. Investigators in the Food Safety Inspection Unit conduct regulatory inspections of food manufacturers and other licensees, to verify compliance with California statutes and regulations. Investigators take enforcement actions against adulterated or mislabeled foods to ensure that the public is protected from exposure to these products.

The Emergency Response Unit responds to food-borne outbreaks, conducts environmental investigations to determine the cause, conducts trace-backs and trace-forwards of contaminated products and oversees recalls of adulterated foods.

The Industry Education and Training Unit develops and provides training to the food manufacturing industry on a variety of important food safety topics such as recall preparedness, and best production practices for specific commodities (sprouts, leafy greens). The Industry Education and Training Unit collaborates with academia, federal, state and local agencies and industry representatives to develop food safety training for the California food industry.



## Protecting California's Drug, Medical Device, Cosmetic and Consumer Products Through Effective Inspection and Enforcement

The Drug, Medical Device and Consumer Product Safety Section employs 60 staff consisting of Peace Officers and Doctoral level scientists and licenses 3,800 drug, medical device and cosmetic manufacturers and Home Medical Device Retailer (HMDR) facilities. The section additionally administers the Stop Tobacco Access to Kids (STAKE) Program regulating the sale of tobacco products, to prevent sales to children under the age of 18 by tobacco retailers.



The Drug Safety Unit (DSU) conducts inspections of pharmaceutical and cosmetic manufacturers within California and takes enforcement actions against any contaminated or misbranded products. DSU enforces both federal and state laws relating to the production of drugs approved for use in the U.S., including the federal Prescription Drug Marketing Act (PDMA). The PDMA includes language that seeks to reduce the occurrence of counterfeit prescription drug production and drug diversion by assuring that principle employees of drug manufacturing companies are not convicted felons or otherwise unqualified to handle prescriptions drugs.

Since passage of the California Hazardous Substances Act in 1961, FDB has taken an integrated public health approach to protecting the public against an array of consumer products containing toxic chemicals, biologic hazards, and physical hazards. This integrated approach leverages its existing public health and regulatory resources.



Activities in the area of household consumer product safety include performing in-depth investigations and “recall effectiveness checks.” These investigations and checks help protect consumers from injuries or illnesses from defective or otherwise unsafe household products by verifying their removal from

commerce. In addition to the Hazardous Substances Act, which bans the sale and distribution of certain hazardous household substances and children's products, FDB enforces the Infant Crib Safety Act, the Bunk Bed Safety Act, the Poison Prevention Packaging Act, Lead in Tableware, and the Children’s Poison Prevention Packaging Act. Further, California’s toy safety statutes enforced by FDB govern the manufacture, sale, and exchange of any toy that is contaminated with any toxic substance.



The Medical Device Safety Unit (MDSU) conducts regulatory inspections of over 1,000 medical device manufacturing facilities and 2,000 HMDR facilities in California to ensure that firms are following all statutory requirements to produce and sale safe and effective medical devices and medical devices and equipment used in the home such as hospital beds, wheelchairs, and Powered Air Purifying Respirators. MDSU also licenses qualified individuals associated with a HMDR facility who dispense prescription medical devices. These individuals are called exemptees.

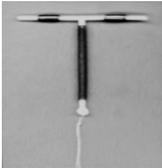


Medical device manufacturers are inspected to assure that medical devices produced are safe and effective for their intended use. These manufacturers can be as simplistic as a one-person operation cutting silicone sheeting into various



sizes for use in general and plastic surgery to a complex multi-building campus with certified clean rooms and sterilization chambers to produce pacemakers and implanted defibrillators.

HMDR facilities are inspected to ensure medical devices and medical oxygen sold or rented by these retail facilities are properly maintained and calibrated, properly stored and dispensed, and are not contaminated. These inspections



also help identify facilities that defraud Medi-Cal, Medicare, and insurance companies with false services and sales of medical devices, and fraudulent billing practices. Participation in joint task forces between agencies provides a forum for sharing information and collaborative enforcement efforts.



### **Protecting California’s Children Through Enforcement of Tobacco Sales Laws**

The Stop Tobacco Access to Kids Enforcement (STAKE) Program regulates the sale of tobacco products to children under the age of 18 by tobacco retailers. STAKE investigators perform undercover compliance checks of approximately 2,000 tobacco retailers each year, using underage youth volunteers, to determine if they are selling to underage children. If sales are made, the tobacco retailer is fined. The checks are recorded on videotape and Peace Officer investigators accompany the underage decoys during the attempted purchase. This activity serves as a deterrent to selling tobacco products to children and identifies specific firms, chains, or types of facilities that have repeated sales to minors so that more aggressive enforcement steps can be taken. Funding for this program comes from a settlement agreement with the tobacco industry through the Federal Government.



### **Supporting Food and Drug Branch Operations**

The Financial Operations & Program Support Section (FOPS) provides the administrative support for the Food and Drug Branch (FDB). FOPS manages the FDB budget, composed of eight funding sources which include, General Fund, Federal Funds, Reimbursements, and Special Funds. FOPS negotiates and manages contracts, conducts personnel transactions, purchasing, legislation, budget change proposals, accounting, vehicle fleet administration, cashiering, employee training and other administrative functions. In addition to serving as the administration arm of FDB, FOPS staff work with FDB programs and field staff to process license applications and also answer questions from companies doing business in California.

## **Ensuring the Safety of Exported Foods, Drugs, and Medical Devices**

Many countries require importers to present an export certificate issued by the California Department of Public Health, Food and Drug Branch (FDB). The Export Document Program was first established in 1990 in response to many countries requiring state certification before allowing foods, drugs, or medical devices into their country. The Export Document Program ensures that exporters of foods, drugs, and medical devices comply with all state and federal statutes ensuring good manufacturing practices and labeling. The workload of the Export Document Program has increased significantly since 1990, as more and more countries require certification from state food programs.

# The Strategic Planning Process

The strategic planning process provided the Food & Drug Branch with an opportunity to review trends and issues, industry patterns, and current practices in the field. For this reason we brought a wide array of staff from all levels of the organization together to analyze and plan as a team. As a team, we conducted an analysis on the backdrop of presentations regarding industry trends, science and economic forecasts.

The draft plan was posted online for all staff to review and provide input. The plan will be presented to industry groups and other stake holders, and their input will be requested as continuous improvement cycles are implemented.

The Strategic Planning Team developed the answers to the questions of:

- What will our success look and feel like in the future? (Vision)
- What is the purpose for which we exist? (Mission)
- Who are we and what do we believe about how we should work together? (Core Values)
- What are our mission critical initiatives? (Goals)
- What are major strategies for achieving our goals? (Sub-Goals)
- What do we need to do to make it happen? (Objectives)

We thank the entire staff of the Branch for their input and ideas and especially thank the members of the FDB 2010 Strategic Planning Team for the time and effort they volunteered to the process. The members of the team included:

Michael Ayala  
Lynne Bittnoff  
Lottie Bloxsom  
Mary Buan  
Maria Bustamante  
Hugo Cornejo  
Robert Glandian  
June-Mei Han  
Minh Huynh  
Pat Kennelly  
Jack Kirk  
Kim Luong  
David Mazzera  
Sylvester Okeke  
Daniel Seid  
Jeff Seid  
Ingeborg Small  
Laurence Upjohn  
Rodney Vienna

**California Department of Public Health  
Food & Drug Branch  
2010 Strategic Plan**

April 30, 2010

## **Vision:**

As public health and safety professionals, we are building the world's best and most respected food, drug, medical device, cosmetics, youth tobacco access enforcement and consumer product safety programs. Our product is an improved quality of life for all California residents.

## **Mission:**

The Food and Drug Branch (FDB) is a science-based law enforcement agency responsible for protecting the public health by assuring the safety, efficacy, and security of food, drugs, medical devices, cosmetics, and consumer products. The Branch conducts routine licensing, training, inspections, investigations and enforcement activities related to regulated commodities, and youth tobacco access, as well as providing emergency and technical assistance in preventing and/or responding to public health threats.

# Core Values:

## **Honesty, Ethics, & Integrity**

We adhere to the highest standards of professional honesty, ethics and integrity in our work and working relationships, so that we earn the trust the public has placed in us.

## **Professional Competence**

We continually develop and sharpen our skills to work efficiently and effectively to achieve our mission

## **Empowerment**

We value our employees and respect each one as a full partner in achieving our goals. Our dedicated employees are our greatest assets. We value different perspectives. We believe that each employee is empowered to act, to treat everyone with honesty, respect and dignity, and to grow. We challenge and empower ourselves, and our colleagues to take personal initiative to achieve legendary excellence in our areas of expertise.

## **Open Collaboration Communication**

We bring transparency and synergism to our work through the open and collaborative exchange of information and ideas. We believe in taking a problem-solving rather than confrontational approach. We must communicate effectively if we are to carry out our mission and achieve what we have envisioned.

## **Teamwork**

We strive to maximize strengths through unity by working in cooperative teams throughout the Branch. We are more effective when information flows freely, teamwork is encouraged, and employee contributions are recognized. We listen with sincerity, trust and objectivity.

## **Continuous Improvement & Innovation**

We believe that our system of service delivery can always be improved, and we will continuously work at ensuring that constant improvement is achieved. We believe in going beyond what is expected. We seek to do things right the first time. We strive to be visionary thinkers and enablers of change.

## **Partnerships**

We believe our program shares the goals of other public, private, and non-profit organizations. Through collaboration, we can ensure appropriate use of resources, and provide needed public services.

# Goals:

**GOAL #1: Program Development**

Augment and enhance FDB programs to provide improved health protection for California citizens.

**GOAL #2: Information Technology:**

Develop the FDB information technology capacity to leverage emerging electronic solutions for efficiencies in critical Branch functions.

**GOAL #3: Workforce Development and Succession:**

Ensure a strong commitment to continuous and accountable workforce development throughout FDB.

**GOAL #4: Business Process Development:**

Seek to streamline and improve both internal and external business processes to ensure the comprehensive completion of all mandated, department-owned, administrative tasks.

# Goals & Objectives:

## **GOAL #1: Program Development**

Augment and enhance Food and Drug Branch programs to provide improved health protection for California citizens.

### **Sub Goal 1.1:**

Develop a statewide retail food safety program that enhances the implementation of retail food safety programs by local health agencies.

**Objective 1:** Seek partnership from industry associations and local health programs to support a statewide retail food safety program by 12/31/2010.

**Objective 2:** Develop a funding strategy that will provide a stable source of revenue to support the program by 12/21/2011.

**Objective 3:** Develop and submit a legislative proposal that will establish a stable funding source for the statewide retail food safety program 6/30/2012.

**Objective 4:** Provide technical support during the legislative process and prepare necessary budgetary change proposals for funding and staff augmentation by 9/30/2013.

### **Sub Goal 1.2:**

Augment emergency response capacity to enable rapid and effective response to emergencies, illness outbreaks or tampering involving FDB regulated commodities.

**Objective 1:** Provide technical training in drug, device, cosmetic and consumer product emergency response to outbreaks, tamperings or other emergencies to program staff by 12/31/2011.

**Objective 2:** Gather and evaluate data regarding response activities and prepare a budgetary change proposal to request additional personnel and appropriation to support critical program activities by 8/31/2012.

**Objective 3:** Revise current emergency response procedures to include product specific response activities for non-food regulated commodities by 12/31/2013.

**Sub Goal 1.3:**

Increase capacity to effectively respond to recalls involving all FDB regulated commodities.

**Objective 1:** Provide technical training in drug, device, cosmetic and consumer product recalls to program staff by 12/31/2011.

**Objective 2:** Gather and evaluate data regarding recall activities and prepare a budgetary change proposal to request additional personnel and appropriation to support critical program activities by 8/31/2012.

**Objective 3:** Revise current recall procedures to include product specific response activities for non-food regulated commodities by 12/31/2013.

**Sub Goal 1.4:**

Establish a cosmetic safety compliance program.

**Objective 1:** Seek partnership from industry trade associations to support a statewide cosmetic safety program 06/30/2011.

**Objective 2:** Develop a legislative proposal to amend existing law and change voluntary cosmetic registration to mandatory registration by 4/30/2012.

**Objective 3:** Provide technical support during the legislative process and prepare necessary budgetary change proposals for funding and staff augmentation by 9/30/2013

**Sub Goal 1.5:**

Augment FDB's Consumer Product Safety Program to ensure effective response and oversight to consumer product issues.

**Objective 1:** Develop a funding strategy that will provide a stable source of revenue to support the program by 12/21/2011.

**Objective 2:** Develop procedures to conduct consumer product inspections, sampling, enforcement, and complaint investigation activities by 12/31/2013.

**Objective 3:** Gather and evaluate data regarding consumer product activities and prepare a budgetary change proposal to request additional personnel and appropriation to support critical program activities by 8/31/2012

## **GOAL #2: Information Technology:**

Develop the FDB IT capacity to leverage emerging electronic solutions for efficiencies in critical Branch functions.

**Objective 1:** Participate in CDPH EOL initiative and transition FDB to automated enterprise online systems by 2014.

## **GOAL #3: Workforce Development and Succession:**

Ensure a strong commitment to continuous and accountable workforce development throughout the Food and Drug Branch.

### **Sub Goal 3.1:**

Establish a Workforce Development Planning Assessment Team.

**Objective 1:** Select members of the work team by 10/1/2010

**Objective 2:** Identify a model agency (or agencies) to examine their training programs by 12/31/2011.

**Objective 3:** Identify a model agency (or agencies) to examine their quality system programs by 12/31/2011.

**Objective 4:** Conduct a Branch Training Assessment to identify baseline training of all FDB staff by 12/31/2011.

**Objective 5.** Develop a Branch Strategic Training Plan by 7/1/2012.

**Objective 6.** Develop a Branch Quality Assurance Continuous Improvement Plan by 7/1/2012.

### **Sub Goal 3.2:**

Establish a Branch Succession Planning Team

**Objective 1:** Select members of the work team by 10/1/2010

**Objective 2.** Conduct a Branch Succession Planning needs assessment by 12/31/2011.

**Objective 3.** Develop a Branch Strategic Succession Plan by 7/1/2012.

#### **GOAL #4: Business Process Development:**

Seek to streamline and improve both internal and external business processes to ensure the comprehensive completion of all mandated, department-owned, administrative tasks.

**Objective 1:** Strengthen & improve current business processes by identifying key improvements needed & making improvements by fully utilizing existing tools and technology to minimize, and eliminate common barriers to accomplishing fundamental tasks by 07/01/2011.

**Objective 2:** Achieve measurable improvements in communications and partnering relationships between Branch Administration and key client-based, internal Department support programs through development of clearly defined roles, expectations, and responsibilities by 07/01/2011.

