APPENDIX D: Integrated Partnership Agreement

PARTNERSHIP AGREEMENT
(Integrated Model)

Background

Today's food safety regulatory structure is a system that consists of multiple government oversight of the food industry and the foods they produce, distribute and sell. This system, with an infrastructure that includes federal, state and local government as participants, has served the public extremely well and we proudly boast to have the safest food supply in the world. While the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are viewed as the major food safety regulatory agencies in the United States, it is state and local government programs that conduct more than 80% of the food establishment inspections, investigate the majority of foodborne illnesses and sample the majority of food products for bacteriological or chemical defects. This is an enormous task and responsibility.

To ensure the public of a safe, wholesome and properly represented food supply, an effective food safety system must be a combined effort of the food industry, the government (at all levels) and the consumer. Surveillance, research, risk assessment, effective regulations with science-based regulatory standards, appropriate inspection, enforcement and compliance activities, training and education must be the cornerstones of any future food safety system. If there is a system breakdown resulting in foodborne illness, the industry must have the willingness and government must have the flexibility and the capacity to move swiftly to determine the cause of the illness, remove the implicated product from the marketplace and build in strategies to prevent future recurrences.

One of the roles of the federal government within this food safety system is to provide leadership through surveillance, technical support, setting of standards, risk assessment, evaluation of programs, certification of field personnel, training and additional funding where needed. One of the major roles of the states and local governments is to perform domestic inspections, investigations and collections of samples. The integrated partnership is one of coordination and uniformity resulting in the elimination of duplicative efforts and better utilization of all current dedicated food safety resources. It is NOT a program to take inspectional responsibilities away from FDA and it does NOT preclude any contracted work between FDA and a state agency.

An integrated partnership must be flexible to accommodate specific needs of FDA Districts or Regions. Furthermore, these partnerships should be written for multiple years and evaluated or adjusted at least annually. Any funding programmed into the partnership would need annual negotiating whereas unfunded portions could continue on.

The dwindling resources available for government services mandate that government at all levels develop effective ways to work smarter and more cooperatively in the regulation of food. FDA and the states have a long history of working together through various contracts, grants, memoranda of understanding and, most recently, partnerships. An integrated partnership goes beyond these mechanisms and begins the development of a blueprint for a fully integrated national food safety system.

PURPOSE

The purpose of this document is to establish a partnership agreement which will coordinate the food protection efforts of the ***(Identify state agency)*** and the U.S. Food and Drug Administration (FDA). This agreement is intended to reduce consumer risk, eliminate duplication, define regulatory roles, and improve channels of communication. All food establishments, (retail, manufacturing, processing, and storage) licensed or permitted by the ***(identify state agency)*** are covered by this agreement. This agreement is a pilot to demonstrate the effectiveness of totally integrating the federal/state responsibility

for the food manufacturing and storage industries in addition to current state/local retail food responsibility.

DURATION OF THE AGREEMENT

Due to the long-term program development aspects of this agreement, it is the intent of both parties that partnership agreement continue in effect for at least five years. This should insure that there will be sufficient time to measure the program outcome resulting from the partnership agreement. It is anticipated that mutually agreed upon modifications to the agreement will be made as needed. Either party may withdraw from the agreement at any time by providing written notification to the other party.

DECLARATION OF ROLES

The ***(identify state agency)*** and the local jurisdictions subject to oversight by the ***(identify state agency)*** have full responsibility for the direct inspection of all food establishments licensed or permitted by the ***(identify state agency)***. When hazards are identified which place the consuming public at risk, the state will initiate appropriate action, in accordance with state law, to eliminate those hazards. In the event the remedies available under state law fail to eliminate a consumer hazard, the ***(identify state agency)*** may request assistance from the FDA if the establishment is subject to regulation under the U.S. Food, Drug and Cosmetic Act.

The FDA also has responsibility for the direct inspection of food manufacturing and storage facilities. They too, will initiate appropriate action in accordance with federal law to eliminate hazards which place the consuming public at risk. FDA and ***(identify state agency)*** will coordinate work plans during this five year period for the purpose of eliminating duplication of inspection efforts.

The FDA will also assume a supportive role designed to assist ***(identify state agency)*** achieve its maximum program potential. FDA will provide training, technical support, lab support, program evaluation, and other assistance as outlined in this agreement. When mutually agreed upon, FDA may assist in regulatory actions when the remedies available under state law have been exhausted or when state personnel lack the technical expertise necessary for a specific task.

CONTENTS OF AGREEMENT

This partnership agreement contains the following functional elements of an integrated food safety system for the State of ***(identify state)***:

A. Planning and Operational Coordination
B. Information Sharing
C. Inspections
D. Food Sampling and Analysis
E. Food Recall Activities
F. Emergency Response Plan

A. PLANNING AND OPERATIONAL COORDINATION

1. **Partnership Purpose and Goals**

   The purpose of this section is to provide uniform, non-duplicative inspectional coverage of the food industry in the State of ***(identify state)*** to achieve maximum consumer protection. This agreement will provide joint operational and communication efforts to coordinate consumer protection services. It will include the sharing of food sanitation inspection reports and/or summaries for all instances of non-compliance with either state or federal law/regulations.

   Partners will optimize the use of personnel, equipment, and facilities to ensure the rapid sharing of critical information in an effort to enhance and reduce duplicate coverage by

federal and state officials.

Implementation of agreed activities will promote a level of interagency cooperation needed to successfully achieve common goals in public health.

2. **Responsibility**

Joint

a. ***Sharing Inventory Information***
On an ad hoc basis, partners will share information from their establishment inventories to assist each other in their enforcement of food establishments.

b. ***Special Projects and Emergencies***
Each party will share information about emerging violative situations in food establishments for which both agencies have jurisdiction. To provide for maximum consumer protection, ***(identify state agency)*** and FDA will coordinate interagency activities to respond promptly and effectively to these situations. This may include sharing of personnel and any other appropriate resources.

c. ***Sharing of Inspectional Programs and Objectives***
Partners will share information on enforcement objectives, programs, and work plans relating to food industries and establishments.

d. ***Dissemination of Critical Information***
Partners will continue to share information about emergencies, recalls, and other inspectional findings which could potentially impact on food products for production or distribution in ***(identify state)***. Guidance for sharing emergency and recall information is outlined in the Food Recall section of this Partnership Agreement.

e. ***Training Activities***
Partners will explore the possibility of joint training activities for investigators. These training programs may focus on emerging regulation or an update on existing policies and/or procedures.

f. ***Regulatory Actions***
In food-related legal actions where both agencies are involved, they will communicate closely throughout the entire procedure. Supporting documents will be shared between the agencies, and when necessary, personnel will be made available for court testimony. Partners will individually fund their own expenses associated with the actions.

U.S. Food and Drug Administration

a. FDA will continue to foster and maintain a comprehensive program to commission ***(identify state agency)*** officials so as to enable them to utilize federal authority and review confidential documents.

b. Summaries of food inspections performed by FDA will be shared with ***(identify state)***.

c. FDA will provide inspection and analytical assistance for follow-up inspections at the request of ***(identify state agency)*** where resources are available.

(Identify State Agency)

Seizures or Embargoes Based on FDA Findings

(Identify state agency) may seize adulterated food products based on findings presented by FDA, if:

a. State monies and resources are available, and

b. statutory authority justifies the seizure, in that the product is adulterated or misbranded as defined in ***(identify state)*** law and regulations. FDA will provide a complete outline of inspectional and/or analytical findings in connection with each request for ***(identify state agency)*** seizures or embargo. Unless the violation is obvious (e.g. rodent gnawing, bird droppings, insect infestation) or FDA has provided sufficient evidence of the violation, ***(identify state agency)*** may follow-up on the seizure request by developing its own evidence on an "as needed" basis. In most cases, this will involve the collection and analysis of samples or embargo by officials.

(Identify state agency) may also proceed with arrangements for hearings involving seized commodities in accordance with ***(identify state agency)*** policy and as provided in State Law.

c. ***Training***
Provide a training site for joint inspection training.

3. **Planned Resources**

a. ***Inspections***
Partners will individually fund inspections performed from operating budgets.

b. ***Personnel***
FDA: Provide officials as needed for training and audit functions.

(Identify state agency): Provide necessary personnel to accomplish the agreed upon activities in the allotted time frames.

4. **Assessment Mechanisms**

a. Evaluate annually the extent to which the agreement enhances the sharing of inspectional resources.

b. Evaluate annually the extent to which sharing of inspectional information achieves maximum consumer protection in ***(identify state)***.

c. Comments from FDA and ***(identify state agency)*** field inspectors as they impact on this agreement will be encouraged and kept on file for consideration at the annual evaluation.

B. INFORMATION SHARING

1. **Partnership Purpose and Goals**

The goals of this section are:

a. To provide FDA reference materials to ***(identify state agency)***.

The FDA develops a number of resource documents designed for field employees to utilize while performing field activities, including, but not limited to inspections, investigations, sample collections, and answering inquiries. FDA also develops resources for cooperating state regulatory officials to use when performing operations pertaining to commodities subject to FDA regulation.

b. To have the FDA District forward ***(identify state agency)*** surveillance reports to the responsible FDA District Office when the manufacturer/distributor of the violative product is not located within the jurisdiction of the ***(identify state)*** District Office.

(Identify state agency) routinely samples suspect food products at establishments throughout ***(identify state)***. When violations are encountered, appropriate action is initiated by ***(identify state agency)*** at the establishment where the sample was collected, and at the responsible manufacturer/shipper if located within the state. If the responsible manufacturer/shipper is located outside ***(identify state)***, ***(identify state agency)*** is limited in what it can do to correct the problem at the source except to notify the responsible party, and request correction and/or removal from the ***(identify state)***. ***(identify state)***.shall provide FDA with copies of these notifications and requests for correction and/or removal.

c. To provide ***(identify state agency)*** resource documents that enhance or conflict with FDA documentation.

2. **Responsibilities**

Joint

a. Meet annually to discuss the outcome of current partnership agreements and to evaluate the usefulness of the partnership agreement and make modifications, as needed.

b. Maintain open dialogue to assure the goals of this agreement are met.

c. To discuss the outcome of current partnership agreements at an annually held meeting.

d. To identify new areas for developing partnership activities and agreements.

U.S. Food and Drug Administration

The FDA District Office will prepare a summary of surveillance reports received from ***(identify state agency)*** and a summary of the FDA resource documents provided to ***(identify state agency)***.

a. ***Surveillance Documents***
The FDA will review and forward to the appropriate FDA District Offices the surveillance documents provided by ***(identify state agency)***. Feedback from those districts pertaining to activities prompted by the surveillance reports will be solicited and shared with appropriate commissioned ***(identify state agency)*** officials.

(n.b., FDA reports and correspondence have not been purged under the Freedom of Information Act, and may contain trade secrets and other information unsuitable for distribution. These documents remain the property of FDA. They are shared with ***(identify state agency)*** for law enforcement purposes and are not to be further divulged.)

b. ***Information Resources***
To the extent resources permit, provide to ***(identify state agency)*** reference and resource materials, including, but not limited to:

- Eureka! Database – a database published monthly on CD-ROM containing FDA policy documents and regulations.
- Retrieval software needed to support the Eureka! Database, and
- FDA reference and training manuals.

(Identify State Agency)

a. ***Surveillance Documents***
When ***(identify state agency)*** encounters products which do not comply with ***(identify state agency)*** regulations and follow-up at an establishment not located within ***(identify state agency)*** jurisdiction is appropriate, ***(identify state agency)*** will forward to the FDA District Office copies of the following documents.

- ***(Identify state agency)*** letter informing firm of the violation
- ***(Identify state agency)*** Report of Sampling and Analysis
- Product Label
- All correspondence between the establishment and ***(identify state agency)***
- Other relevant ***(identify state agency)*** forms related to the incident

(n.b., This agreement does not preclude ***(identify state agency)*** from contacting the FDA District Office about a ***(identify state)*** establishment if a joint investigation appears to be warranted.)

b. ***Information Resources***
To the extent resources permit, provide to FDA reference and resource materials.

3. **Planned Resources**

a. ***Funding***
When funds are available, FDA will cover the expenses incurred by ***(identify state agency)*** officials attending the annual meeting, as well as related meeting expenses.

b. ***Personnel***

Joint
Both agencies will provide the personnel needed to monitor the partnership agreements and to complete the activities listed in the partnership agreements.

U.S. Food and Drug Administration
FDA will provide management and clerical support needed to process the ***(identify state agency)*** surveillance documents and to furnish ***(identify state agency)*** with the FDA reference materials.

(Identify State Agency)
(Identify state agency) will provide the clerical support needed to furnish FDA with copies of the surveillance documents.

4. **Assessment Mechanisms**

The evaluation will include a summary of surveillance reports received from ***(identify state agency)*** and a summary of the FDA resource documents provided to ***(identify state agency)***.

A separate evaluation will be completed for the FDA – ***(identify state agency)*** annual meeting.

The contact persons from both agencies will consult periodically to discuss the value of the information exchange. Recommendations for improvement will be considered.

C. INSPECTIONS

1. **Partnership Purpose and Goals**

The goal of this section is to eliminate duplicative efforts for inspections of food establishments in ***(Identify state)*** and to better utilize dedicated resources within the inspection programs of FDA and ***(identify state agency)***.

Partners will optimize the use of inspection data and equipment to ensure complete coverage of ***(identify state)*** food establishments.

2. **Responsibility**

Joint

a. The ***(identify state agency)*** and FDA agree to inspect all food establishments, as defined by state or federal law, to determine if the operations critical to the production and service of safe foods are in compliance with state or federal regulations. When significant violations are identified which are not in compliance with state or federal requirements, corrective action will be required in accordance with appropriate regulations and administrative procedures.

The ***(identify state agency)*** and FDA agree to share summaries or copies of food inspection reports as predetermined to be accomplished by both agencies. The establishments selected for inspection will be performed by the appropriate agency or jointly. A yearly coordinated inspection plan will be utilized.

b. The ***(identify state agency)*** and FDA agree to prioritize the inspection frequency for each food establishment licensed or permitted by the state, based on the potential health hazard associated with each establishment's operation and their compliance history. Two priority groups will be established (high and low) and program resources will be allocated accordingly. The following guidelines will be followed:

High Priority

-Low acid canned food manufacturers
-Acidified food manufacturers
-Food salvagers
-Wholesale manufacturers of potentially hazardous foods (i.e., cream-filled pastries, filled macaroni products, smoked/ cured fish)
-Manufacturers of high risk ready-to-eat foods
-Vacuum packers
-Food service establishments

Rate: ___ inspections per year (minimum) ***Reinspect: ___ days***

Low Priority

-All other food manufacturers
-Refrigerated warehouses
-Grocery stores
-Food warehouses

Rate: ___ inspection per year (minimum) ***Reinspect: ___ days***

c. FDA and ***(identify state agency)*** agree to collect appropriate samples based on inspectional findings to support enforcement action.

d. FDA agrees to refer all food related complaints of food establishment assigned to the ***(identify state agency)*** for investigation. The ***(identify state agency)*** will refer all food related complaints of food establishments assigned to FDA for investigation. When illness or injury is alleged, agencies agree to conduct an immediate investigation and keep the other agency informed during the course of the investigation. Within ten working days after the conclusion of the investigation a written report of the findings will be provided to the other agency. When serious public health concerns arise FDA may elect to initiate a joint investigation in which case FDA would prepare the final written report.

e. FDA agrees to provide laboratory support to ***(identify state agency)*** for foodborne illness investigations and regulatory actions. Support will be limited to procedures necessary to the investigation which cannot be performed in the ***(identify state agency)*** lab. The ***(identify state agency)*** agrees to provide similar service for FDA where appropriate.

f. Inspection techniques consistent with nationally recognized standards will be employed by FDA and ***(identify state agency)*** personnel conducting the inspections covered by this agreement.

g. FDA and ***(identify state agency)*** agree to take appropriate follow-up enforcement action against food establishments inspected and found to be in violation of their law.

U.S. Food and Drug Administration

a. FDA agrees to train and certify an appropriate number of ***(identify state agency)*** State Evaluation Officers (SEO). The SEO will conduct Hazard Analysis Critical Control Point (HACCP) based program evaluations of the major program sub-units in the state. The same approach will be used for all types of food establishments (retail, manufacturing, storage, etc.).

b. FDA agrees to conduct joint audit inspections annually with each SEO. The joint audit inspections will serve the dual roles of program validation and recertification of the SEOs.

(Identify State Agency)

a. ***(Identify state agency)*** agrees to provide FDA with an annual summary of all food protection program activities conducted by the state and/or local regulatory personnel.

b. ***(Identify state agency)*** agrees to evaluate at least 50% of the program sub-units each year. The evaluations will be based on HACCP principles and designed to

measure the compliance level of critical control points (CCPs) and control points (CPs) in various types of food establishments. Written reports will be prepared after each field evaluation. The written reports will identify areas which pose serious risks to consumer health and make recommendations for corrective action. The report format will be developed jointly to insure it meets the needs of all parties concerned. Evaluations will only be performed by FDA Certified State Evaluation Officers. Copies of the state evaluation reports will be provided to FDA after the findings have been discussed with the appropriate state or local program manager. The data contained in the evaluation reports will be used to update FDA's baseline evaluation data.

Internal program evaluation is essential to effective program operation. FDA will support annual ***(identify state agency)*** program evaluations subject to resource availability. Supplemental agreements for this purpose will be negotiated on an annual basis.

3. **Planned Resources**

   a. FDA and ***(identify state agency)*** will provide the necessary personnel to accomplish the agreed upon inspection activities.

   b. Partners will individually fund inspections from their operating budgets.

   c. All persons performing the food inspections will have completed the training program as prescribed by the applicable national criteria for training.

4. **Assessment Mechanisms**

   a. ***(Identify state agency)*** and FDA agree to conduct an annual planning conference for state and local regulatory personnel to review the results of state program evaluations and FDA audits. The conference will include focused training and program planning sessions designed to address program concerns and new technology.

   b. Continuing staff training, which focuses upon program weaknesses identified in the evaluation process and emerging problems, is essential to long-term program development. FDA will support annual ***(identify state agency)*** staff planning/training conferences subject to resource availability. Supplemental agreements for this purpose will be negotiated on an annual basis.

   c. Partners will evaluate annually the extent to which the agreement enhances the goals outlined in this section.

D. FOOD SAMPLING AND ANALYSIS

1. **Partnership Purpose and Goals**

The goal of this section is to broaden the scope of coverage of foods produced and marketed in ***(identify state)*** to achieve maximum consumer protection. The joint operational and communication efforts will provide coordinated consumer protection, including the most effective application of both ***(identify state)*** and federal statutes.

The ***(identify state agency)*** and FDA may need to identify differences in sampling specifications and methods of analysis in certain instances.

Food sampling program areas covered under this section include the following:

-Mycotoxin sampling
-Pesticide sampling
-Food microbiology
-Food Chemistry
-HACCP verification
-Foreign imports

2. **Responsibility**

Joint

a. Food samples collected will be analyzed at both the FDA and ***(identify state agency)*** laboratory as mutually agreed upon.

b. FDA and ***(identify state agency)*** will share available surveillance information related to domestic and imported food products.

c. FDA and ***(identify state agency)*** will ensure suitable logistics for sample delivery.

d. FDA and ***(identify state agency)*** will perform follow-up sampling or enforcement action where deemed necessary.

e. FDA and ***(identify state agency)*** will report voluntary or compulsory enforcement actions taken as a result of sampling conducted.

U.S. Food and Drug Administration

a. FDA will provide ***(identify state agency)*** a list of foods to be sampled and analyzed.

b. For each food to be sampled, FDA will provide the ***(identify state agency)*** with sufficient information to assure the proper identification, location, and amount of the lot to be sampled.

c. FDA will provide equipment needed for special sampling, i.e., sterile containers.

d. FDA will ensure ***(identify state)*** food inspectors are kept abreast of changes in sample collection techniques and approaches.

e. FDA will provide ***(identify state agency)*** with a final report of the samples collected and the analytical results.

(Identify State Agency)

a. ***(Identify state agency)*** will collect samples at food establishments designated or mutually agreed upon.

b. ***Identify state agency)*** will ensure these samples are collected in a timely fashion or within an agreed upon time frame.

c. ***(Identify state agency)*** will package or transport samples to the appropriate laboratory for analysis.

d. Appropriate FDA forms will be used by ***(identify state agency)*** inspectors.

3. **Planned Resources**

Funding
FDA will reimburse the ***(identify state agency)*** for the cost of services at an agreed upon reimbursable rate associated with each sample collection. This does not include the cost of the sample which is funded directly by FDA.

4. **Assessment Mechanisms**

Final evaluations occur annually and following the end of the agreement period. The evaluation will include a summary of the samples collected and analytical results.

E. FOOD RECALL ACTIVITIES

1. **Partnership Purpose and Goals**

The purpose of this partnership agreement is to ensure prompt removal of non-compliant products from the market. This agreement will provide joint guidelines accepted by both agencies which meet their requirements for coverage of recalls.

Partners will conduct field operations to identify the cause(s) of non-compliance which led to the recall. This information, as well as actions being taken to preclude further non-compliance of this type, will be communicated between both agencies.

This agreement covers the following areas:

a. Share information and copies of documents relating to voluntary and/or agency-initiated recalls, market withdrawals, and any other action related to the removal of domestically produced or imported food products which have entered market channels within ***(identify state)***.

b. Coordinate and jointly plan coverage/monitoring of recall activities to ensure non-compliant products are removed from the market. Duplication of efforts by both agencies will need to be avoided.

c. Train employees in the information required by the recall tracking systems maintained by ***(identify state agency)*** and FDA.

2. **Responsibilities**

Joint

a. The program area for partnership includes the federal and state statutory definitions and requirements for all food products that have either been imported into the United States or domestically produced. Recalls may involve one batch or entry, or an entire product line. The proposed recall must extend to the appropriate market level, and cover all items or product containers that may possibly be contaminated or recalled from market channels manufactured and/or distributed in ***(identify state)***.

b. Agencies will coordinate follow-up inspectional activities, share information about the cause(s) of non-compliance which led to recall of the product, and plan and implement actions needed to ensure violations will not recur.

c. Agencies will coordinate recall audit checks involving consignees in ***(identify state)*** for recalls initiated by firms both within and outside ***(identify state)***. Agencies will

share information regarding the effectiveness of those audit checks.

d. The agreement will not impose additional inspectional requirements on either agency. However, it will provide a means of sharing the information obtained by ***(identify state agency)*** inspectors with FDA.

e. Each party will share information about their recall requirements and reporting systems, as well as food-related enforcement objectives related to those products and establishments requiring focused attention.

f. Partners will explore joint training for field personnel. Training may include an update on how to conduct inspections and field examinations in order to identify the causes and scope of food product recalls.

g. Partners will provide briefing sessions for personnel of the other agency promoting an understanding of each agency's laws, regulations, and methods of approach.

U.S. Food and Drug Administration

a. FDA will fax or electronically send the 24-hour alert, the FDA recall recommendation and notification to the ***(identify state agency)***.

b. FDA will provide ***(identify state agency)*** with a summary of recalls and legal actions which resulted from recalls initiated by ***(identify state agency)*** monitored by the District.

(Identify State Agency)

a. ***(Identify state agency)*** will fax or electronically send the Recall Tracking Report form to the FDA Recall Coordinator. The fax should include the laboratory worksheets if samples were analyzed. The faxed or electronically sent information and additional attachments should then be mailed to the attention of the Recall Coordinator.

b. The Recall Coordinator will send the information to the appropriate FDA District Office. The Recall Coordinator will process all recalls involving firms located in ***(identify state)***.

3. **Planned Resources**

a. ***Funding***
Partners will individually fund inspections and other field operations performed from operating budgets.

b. ***Personnel***
Partners will provide staffing resources as needed to conduct field operations and reporting activities. However, if agreed by both agencies, a food plant inspection may be conducted under an existing state contract.

Partners will provide personnel needed for training and briefing sessions.

4. **Assessment Mechanisms**

a. Evaluate annually the extent to which the agreement enhances sharing of food recall information.

d. Evaluate annually the extent to which sharing of recall information reduces or eliminates the need for follow-up visits to obtain data needed for recall reporting systems.

F. EMERGENCY RESPONSE PLAN

1. **Partnership Purpose and Goals**

In the event of any major natural disaster such as a hurricane, tropical storm, tornado, or flooding, the FDA and the ***(identify state agency)*** agree to work together in a coordinated way to address any food product public health emergency in our mutual areas of responsibility.

The purpose of this partnership is to establish a cooperative emergency response plan in the event of a natural disaster to provide prompt and adequate assessment and control of food products within ***(identify state)*** at the manufacturing, storage and distribution levels. The objective is to protect the public health with efficient use of our joint resources.

The scope of this agreement is not intended to extend to man-made disasters, such as nuclear accidents, bombings, or transportation accidents.

The program area for partnership includes both federal and state responsibility to protect the public food supplies regulated by partners to this agreement within ***(identify state)*** to prevent or reduce public health risks.

Partnership activities will include:

1. Assessment of damage to regulated industry and related products to determine public health risks.
2. Supervision of reconditioning/salvage operations.
3. Supervision of destruction of adulterated products.
4. Embargo/seizure, if required.

2. Responsibilities

Joint

a. Each party will define the disaster area and provide personnel to form assessment teams.

b. Each party will contribute their Official Establishment Inventories (OEI) with firms listed alphabetically by county and city. Each agency will review the OEI to eliminate firms from potential disaster follow-up coverage based on the nature and location of the disaster. Each agency, within their respective jurisdictional responsibilities, will attempt to identify additional firms not in the OEI where regulated products may be located.

c. Each party will inspect each susceptible firm in a disaster area to determine the extent of damage to the facility and extent of adulteration and/or public health risk to regulated products. This activity will be coordinated to provide a systematic approach, to avoid duplication of effort, and to assure assignments are consistent with statutory authorities for the respective jointly participating agencies. Additionally, each party will coordinate and conduct regulatory action, such as embargoes or seizures necessitated by disaster adulteration.

d. Each party shall share documentation for up-to-date tracking of disaster response efforts, and provide sufficient documentation for assessment of the success of the disaster follow-up work. Salvage, reconditioning and/or destruction of disaster affected products will be properly supervised.

e. Follow-up training during each fiscal year that this agreement is in force will be provided.

f. Disaster work summary reports will be prepared and shared between agencies.

U.S. Food and Drug Administration

a. Provide personnel (Consumer Safety Officers, Consumer Safety Inspectors, Analysts) to conduct field assessment of disaster effects and to analyze samples relative to the disaster.

b. Provide vehicles for team use during field assessment/evaluation of disaster effects.

c. Provide cellular phones for use in the event conventional communications are disaster affected.

d. Provide cameras, film, sampling tools/containers, etc., for documentation of adulterated products.

e. Analyze samples collected to document disaster adulteration.

f. Provide facilities for coordinating disaster work.

g. Coordinate with other federal agencies involved in disaster assessment/clean-up, particularly those with MOUs, including those such as the Coast Guard, that could provide water transport vessels as needed.

h. Coordinate with other FDA districts which may be affected by the disaster or which may receive disaster affected products.

i. Recommend seizure of adulterated products when appropriate.

j. Provide instructors for disaster related training.

(Identify State Agency)

a. Supply personnel (state environmentalists, food inspectors, health officials, biologists, etc.) to participate as team members for assessment of disaster effects.

b. Analyze samples collected to document disaster adulteration.

c. Coordinate with other state agencies where appropriate to protect public health.

d. Act as liaison with other appropriate state, county, and local health and law enforcement agencies.

e. Provide embargo power for use as needed during the assessment.

f. Provide facilities for coordinating activities.

g. Provide instructors for joint disaster related training. (This will be provided by the joint agencies themselves or by other state agencies that specialize in such training and generally do not have regulatory authority.

h. Provide vehicles for team or state use during assessment.

i. Provide cameras and film as needed for documentation of adulterated products to complement use of FDA cameras/film.

3. **Planned Resources**

a. ***Funding***
Each agency will fund travel and assessment/reconditioning regulatory oversight activities (including overtime) from its own operating budget within the limitations and constraints of the budgets of the joint agencies.

b. ***Personnel***
FDA will provide sufficient Consumer Safety Officers (CSOs), Consumer Safety Inspectors (CSIs), and Analysts to form federal/state assessment teams, and to provide appropriate analytical support. If necessary, FDA (NOL-DO) will request additional personnel from other FDA districts.

The ***(identify state agency)*** will supply environmentalists and inspection personnel to provide sufficient federal/state teams to provide coverage needed.

4. **Assessment Mechanisms**

a. Completed Natural Disaster Reports (Form FD-2809) or comparable state form will be compared to the affected area OEI to assure complete coverage.

b. Jointly, the partnership coordinators will utilize the Natural Disaster Reports to prepare and maintain a correct database to document the extent of damage from the disaster:

- Cost estimates of damage to facilities and equipment.
- Cost estimates of adulterated products not salvageable.
- Cost estimates of regulated products salvageable.

c. Assessment will be made relating to the cost to each agency, i.e., hours, salaries, overtime, equipment/vehicle usage.

d. Interim evaluation by the partnership coordinators of the success of the disaster response will occur within 30 days following any disaster where partnershipping occurs.

e. An evaluation will be performed annually. The evaluation will reflect the extent to which the partnership maximizes consumer protection, protects or reduces public health risk through assessment of disaster damage to regulated industry and products and the prevention of disaster adulterated raw materials or finished product from reaching the consumer that would otherwise cause a public health risk to consumers of such products.

The evaluation will be performed jointly by the FDA and ***(identify state)*** project coordinators or their designees. The joint effort will be in a form to be chosen by the

project coordinators.

f. Based on the final evaluation, the Project Coordinators will jointly prepare recommendations for future agency action and if appropriate for approval by the signatories to this agreement.