MOU 225-11-0007

MEMORANDUM OF UNDERSTANDING
BETWEEN THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
DEPARTMENT OF LABOR
AND THE FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SHARING HEALTH AND SAFETY INFORMATION RELATED TO FACILITIES WHERE
FOOD IS PRODUCED, PROCESSED, OR HELD

I. PURPOSE
Facilitate information sharing with respect to matters affecting the occupational safety and health of workers and the safety and security of our nation's food supply in facilities where food is produced, processed or held.

II. BACKGROUND
The U.S. Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) recognize the importance of close cooperation and collaboration. On September 16, 2010, the agencies signed a Joint Statement affirming their mutual commitment to sharing relevant health and safety-related information and exploring options to establish formal communication procedures.

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (FFDCA) and other laws. In fulfilling its responsibilities under the FFDCA, FDA's activities are directed toward protecting the public health by ensuring that foods are safe and wholesome and truthfully and informatively labeled. This is accomplished, in part, by inspecting the production, processing, and distribution of foods and examining samples thereof to ensure compliance with applicable requirements.

OSHA is charged with the enforcement of the Occupational Safety and Health Act of 1970 (OSH Act), under which employers are responsible for providing safe and healthful workplaces for their employees. OSHA's role is to assure these conditions for America's working men and women by setting and enforcing standards, and providing training, education and assistance.

When inspecting food facilities in furtherance of their responsibilities, FDA investigators and OSHA compliance officers may observe conditions or obtain information relevant to the other agency's safety or health mission. FDA and OSHA are committed to sharing information on health or safety-related problems that are relevant to the regulatory and enforcement responsibilities of the other agency.

III. SUBSTANCE OF THE AGREEMENT
The FDA and OSHA will share relevant information with each other, while ensuring that the exchange of such information complies with applicable law.

A. Referrals of Information

In accordance with the Information Sharing provisions under Section IV, the parties agree to the following:

If FDA, in its investigations of facilities where food is produced, processed or held, has reason to believe that a potential violation of an OSHA standard is present, FDA will provide this information to OSHA. This may include observations made directly by FDA personnel, as well as information received from other parties, including workers. OSHA may provide information that FDA designates as public information with States that operate OSHA-approved State Plans (OSHA State Plan States); non-public information that FDA has provided to OSHA will only be shared with OSHA State PlanStates as approved by FDA in accordance with FDA's disclosure regulations.

If OSHA in its investigations of facilities where food is produced, processed or held has reason to believe that factors are present which may indicate a possible violation of FDA standards, OSHA will provide this information to FDA. This may include observations made directly by OSHA personnel, information provided to OSHA by an OSHA State Plan State, and information received from other parties, including workers.

B. Communication Procedures

The FDA and OSHA agree to develop a practicable process including procedures and criteria for information sharing and a plan for implementation.

C. Training

The FDA and OSHA agree to develop and implement a plan for training appropriate employees.

IV. INFORMATION SHARING

The procedures established under Section III must include proper safeguards against unauthorized use and disclosure of the non-public information exchanged under this MOU. Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be shared and used consistent with the Trade Secrets Act [18 U.S.C. § 1905], the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], the Privacy Act of 1974, as amended [5 U.S.C. § 552a], the Freedom of Information Act (5 U.S.C. § 552], any other applicable Federal law and regulations implementing it. Pursuant to FFDCA section 301(j) [21 U.S.C. *33J(j)],* FDA will not reveal to OSHA any method or process which is entitled to protection as a trade secret. Any Federal partner may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request. See Process for Information Sharing under Appendix A.

Access to the non-public information shared under this MOU shall be restricted to authorized FDA and OSHA employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this MOU, unless authorized in writing by the agency that provided the information or otherwise required by law. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards against unauthorized disclosure of confidential information; and (3) the administrative, civil and criminal penalties contained in applicable Federal laws for the unauthorized disclosure of confidential information.

If an agency that has received information under this MOU receives a Freedom of Information Act (FOIA) request for which there are responsive records that originated with the other agency, to the extent practicable, it will refer that request to the other agency for it to respond directly to the requestor regarding the releasability of the information. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will issue directly from the other agency.

V. LIMITATIONS

This MOU represents the broad outline of the Parties' present intent to collaborate in areas of mutual interest to FDA and OSHA. It does not create binding, enforceable obligations against either Agency. The MOU does not alter, amend, or affect in any way the statutory or regulatory authority of the FDA or OSHA. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing agreements or arrangements between the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and OSHA operate. Nothing in this MOU shall obligate FDA and OSHA to any current expenditure or future expenditure of resources in advance of the availability of appropriations from Congress.

VI. LIAISON OFFICERS

To facilitate the activities carried out under this MOU, each agency will establish a single agency liaison. The initial liaisons will be:

For OSHA: Directorate of Enforcement Programs, OSHA- DOL, 200 Constitution Avenue NW, Washington, D.C. 20210; Telephone: 202-693-2100.

For FDA: Howard Sklamberg, Esq., Director, Office of Enforcement, Office of Regulatory Affairs, FDA- W032 RM 4362, 10903 New Hampshire Avenue, Silver Spring, MD 20993; Telephone: 301-796-8314.

Each agency may designate a new liaison at any time by notifying the other in writing. If at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the agency will name a new liaison and notify the other agency through the designated liaison.

VII. EFFECTIVE DATE

This Memorandum is effective upon signature by the parties. It may be amended at any time by mutual written agreement of the agencies and may be terminated by either agency upon sixty days written notice.

Approved and Accepted
for the U.S. Department of Labor
Signed by: David Michaels
Assistant Secretary for Occupational Safety and Health
Date: June 20, 2011

Approved and Accepted
for the Food and Drug Administration
Signed by: Dara Corrigan
Associate Commissioner for Regulatory Affairs
Date: May 2, 2011

APPENDIX A
Process for Information Sharing

Pursuant to Section 4 of the Memorandum of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) any Federal partner "may decide not to share information or expertise in response to a particular request for information made according to the procedures established under Section 4, or to limit the scope of information and expertise sharing in response to a

particular request." Nothing in the process described below changes Section 4.

When, under the current MOU, staff at the FDA or OSHA request from the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, and need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

"Information that is shared under this request will be under the FDA-OSHA Memorandum of Understanding. We agree not to disclose any shared information in any mauner without your written permission or as required by law with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text."

A response to a request should also be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

"Pursuant to the FDA-OSHA Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any mauner without our express written consent or as required by law with advance notice to the originating agency." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text."