DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0005]

Memorandum of Understanding Between the Food and Drug Administration and the U.S. Department of Agriculture's Agricultural and Marketing Service, Farm Service Agency, and Food Nutrition Service

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) with the U.S. Department of Agriculture's (USDA) Agricultural and Marketing Service, Farm Service Agency, and Food Nutrition Service. The purpose of the MOU is to provide a framework for the parties to communicate and cooperate in the timely and full exchange of information to optimize controls essential to minimizing potential for the distribution or use of USDA foods which may be unsafe. For the purpose of this MOU, the term ''USDA foods'' will mean commodities procured by USDA for use in domestic nutrition assistance programs.

DATES: The agreement became effective September 29, 2011.

FOR FURTHER INFORMATION CONTACT: Jacqueline Little, Office of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg, rm. 4146, Rockville, MD 20857, (301) 796–8204, Fax: (301) 827–3680, Email: *jacqueline.little@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the Agency is publishing notice of this MOU.

Dated: November 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

MOU Number: 225-11-0012

MEMORANDUM OF UNDERSTANDING

Between

UNITED STATES DEPARTMENT OF AGRICULTURE'S AGRICULTURAL MARKETING SERVICE, FARM SERVICE AGENCY, and FOOD AND NUTRITION SERVICE

and

DEPARTMENT OF HEALTH AND HUMAN SERVICES' FOOD AND DRUG ADMINISTRATION

The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS), Farm Service Agency (FSA), Food and Nutrition Service (FNS), and the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), collectively referred to as the Parties, intend to facilitate the exchange of information among the Parties related to FDA-regulated foods procured or subject to procurement by USDA. For the purpose of this Memorandum of Understanding (MOU) the term "USDA Foods" will mean commodities procured by USDA for use in domestic nutrition assistance programs.

I. PURPOSE

The purpose of this MOU is to establish a framework for the Parties to communicate and cooperate in the timely and full exchange of information to optimize controls essential to minimizing potential for the distribution or use of USDA Foods which may be unsafe.

II. STATUTORY AUTHORITIES AND RESPONSIBILITIES

FDA is charged with the enforcement of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 301, et seq.), which defines "food" as any "articles used for food or drink *** [or] for components of any such article" (21 U.S.C. § 321(f)). FDA also implements and enforces the Public Health Service Act (42 U.S.C. § 201, et seq.), the Fair Packaging and Labeling Act (15 U.S.C. § 1451 et seq.), and other statutes. In carrying out its responsibilities under these statutes, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by USDA's Food Safety Inspection Service (FSIS). FDA inspects food and food samples during processing and distribution. When FDA determines that food is not compliant with statutory and regulatory

requirements, FDA works with manufacturers to ensure the removal of the food from the market. FDA can also take enforcement action.

FNS administers the USDA domestic nutrition assistance programs and provides USDA Foods to its programs, such as the National School Lunch Program, the Commodity Supplemental Food Program, The Emergency Food Assistance Program, and the Food Distribution Program on Indian Reservations pursuant to authorities in the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.), the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.), the Agriculture and Consumer Protection Act of 1973 (7 U.S.C. 612c note), and the Emergency Food Assistance Act of 1983 (7 U.S.C. 7501 et seq.).

Pursuant to Section 15 of the Commodity Distribution Reform Act and WIC Amendments of 1987 (7 U.S.C. 612c note), the Secretary of USDA may use funds available to implement Section 32 of the Act of August 24, 1935, (7 U.S.C. 612c), to reimburse State agencies and others for the removal of USDA Foods distributed under a domestic nutrition assistance program if the Secretary determines that the commodities pose a health or safety risk.

USDA, through AMS and FSA, purchases and delivers USDA Foods to State distributing agencies and other entities for donation in the domestic nutrition assistance programs.

In addition to acquiring food products on behalf of FNS using funds appropriated for FNS programs, AMS carries out a wide range of program activities that facilitate the marketing of domestic agricultural products as authorized by Section 32 of the Act of August 24, 1935, the Agricultural Marketing Act of 1946, the Perishable Agricultural Commodities Act, and more than 50 other statutes. Many of the USDA Foods purchased by AMS must meet specific grade and specification requirements established by the various inspections and grading activities of AMS including the Fruit and Vegetable Programs, Poultry Programs, and Livestock and Seed Programs. AMS typically contracts with manufacturers to fulfill program needs. Also, some non-manufacturers participate by utilizing subcontracts to fulfill AMS commodity contracts. AMS procures Group A USDA Foods listed in Appendix A, Section A.

In addition to acquiring food products on behalf of FNS using funds appropriated for FNS programs, FSA is responsible for the management of commodities acquired by the Commodity Credit Corporation under various statutes, including the Food, Conservation and Energy Act of 2008, the Agricultural Act of 1949, as amended, and the Commodity Credit Corporation Charter Act. FSA also contracts for commercial storage and distribution of USDA Foods purchased for the Food Distribution Program on Indian Reservations and the Commodity Supplemental Food Program. FSA procures Group B USDA Foods listed in Appendix A, Section B.

III. SUBSTANCE OF THE AGREEMENT

The Parties agree:

A. FDA, FNS, AMS, and FSA will maintain points of contact (POC) at the headquarters and district office levels, including email distribution lists, to ensure the agencies can respond effectively to questions that arise regarding the safety or security of FDA-regulated USDA Foods. In addition, the Parties agree to inform their respective counterparts annually, or as necessary, of any change in the designated contact persons or changes in the areas of responsibility or in the organization of the agency.

The names of the POCs will be distributed to the managers of FDA, FNS, AMS, and FSA who have relevant responsibilities.

B. FDA, FNS, AMS, and FSA will share in a timely manner among respective liaison offices and contacts (provided for under A above) information and updates on complaints, reports, or events that compromise FDA-regulated USDA Foods and may affect the health and safety of USDA nutrition assistance program recipients, and to cooperate on investigations into the food safety significance of complaints and occurrences of outbreaks of foodborne illness, injuries, or adverse reactions in connection with FDA-regulated USDA Foods.

C. For food products involved in recalls monitored by FDA or subject of an FDA consumer alert, FDA will inquire of the vendor whether the product(s) in question were acquired by any USDA procurement agency or barter partner for use in the domestic nutrition assistance programs. If so, FDA will, in a timely manner, provide to FNS, AMS and FSA complete information about types of FDA-regulated foods procured by USDA that are subject to a recall or an FDA consumer alert, as well as the actual or anticipated distribution of such foods. Upon request, FNS, AMS and FSA will provide information to FDA in a timely manner about how USDA Foods are procured and distributed by USDA.

D. AMS and FSA will cooperate in obtaining samples for analysis by FDA of those FDA-regulated USDA Foods that FDA believes may pose a health risk. FDA will share the analytical results with affected USDA agencies in a timely manner.

E. FDA will share with FNS, in a timely manner, information on FDA's investigations regarding foodborne illnesses linked to FDA-regulated USDA Foods. This information may influence whether a USDA procurement agency will place a hold on certain products, pending the analytical results described in D above, or other FDA scientific conclusions or determinations.

F. When an FDA regulated food that also is a USDA Food is under FDA investigation, FNS will arrange, within 10 business days of notification of the investigation, discussions

between FDA and the affected USDA agencies to determine the course of the FDA investigation and findings. FDA will assist USDA in determining the most appropriate action to take to protect the health of the recipients of the USDA Food(s) in question.

G. FDA and the appropriate USDA agencies will work cooperatively to develop communication strategies, including FDA press releases and stakeholder announcements, for potential references to USDA Foods.

H. AMS and FSA will require all of their vendors to comply with all State and Federal guidelines.

I. As requested by FDA, FNS, AMS, and FSA will assist FDA in conducting recall audits involving FDA-regulated USDA Foods.

IV. INFORMATION SHARING

The terms of this agreement shall include appropriate safeguards against unauthorized use and disclosure of the non-public information exchanged under this MOU. Pursuant to FFDCA section 301(j) [21 U.S.C. 331(j)], FDA will not reveal to FNS, AMS or FSA any method or process which is entitled to protection as a trade secret. FDA, FNS, AMS, and FSA shall establish appropriate safeguards to protect the confidentiality of the information and to prevent unauthorized access to the information provided by other Federal partners. While recognizing that the overall purpose of this MOU is to facilitate information sharing, 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 B.

Access to the information shared under this MOU shall be restricted to authorized FDA, FNS, AMS, and FSA employees and officials who require access to perform their official duties in accordance with the uses of the information as authorized by this MOU. Such personnel shall be advised of (1) the confidential nature of the information and (2) safeguards required to protect the information.

FDA, FNS, AMS, and FSA agree to promptly notify the other Federal partners of any actual or suspected unauthorized disclosure of information shared under this MOU.

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, it will refer the request to the information-sharing agency for it to respond directly to the requestor regarding whether the information can be released. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will be issued directly from the other agency.

V. LIMITATIONS

This MOU represents the broad outline of the Parties' intent to enter into specific agreements for collaborative efforts in areas of mutual interest to FDA, FNS, AMS, and FSA. 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 or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU. This MOU will be subject to the applicable statutes, regulations and policies affecting FDA, FNS, AMS, and FSA.

VI. LIAISON OFFICES AND CONTACTS FOR PARTIES

Recall Operations Staff,
Division of Compliance Management and Operations
Office of Enforcement
Office of Regulatory Affairs
Food and Drug Administration
10903 New Hampshire Avenue
BLDG 32, Room 4353
Silver Spring, MD 20993

Office of Crisis Management
Office of Emergency Operations
Food and Drug Administration
10903 New Hampshire Avenue
Bldg 32
Silver Spring, MD 20993
1-866-300-4374 (24 hours)

USDA FNS
U.S. Department of Agriculture
Food and Nutrition Service
Office of Food Safety
3101 Park Center Drive
Room 628
Alexandria, VA 22302

USDA AMS
U.S. Department of Agriculture
Agricultural Marketing Service
Fruit and Vegetable Programs

1400 Independence Ave., S.W.
Stop 2632
Washington, DC 20250-2632

USDA AMS
U.S. Department of Agriculture
Agricultural Marketing Service
Poultry Programs
1400 Independence Ave., S.W.
Stop 0256
Washington, DC 20250-0256

USDA AMS
U.S. Department of Agriculture
Agricultural Marketing Service
Livestock and Seed Programs
1400 Independence Ave., S.W.
Stop 0249
Washington, DC 20250-0249

USDA FSA
U.S. Department of Agriculture
Farm Service Agency
Deputy Administrator, Commodity Operations
Stop 0550
1400 Independence Ave., S.W.
Washington, DC 20250-0550

VII. EFFECTIVE DATE, DURATION, TERMINATION AND MODIFICATION

This MOU shall become effective upon signature of all Parties and will continue in effect for a period of five years. It will be evaluated after it has been in effect for one year, at which time the agencies agree to explore the feasibility of expanding cooperative activities. The MOU may be extended or modified by mutual written agreement of the Parties. The MOU may be terminated upon a 30-day advance notice by any of the Parties.

VIII. SIGNATURES OF RESPONSIBLE PARTIES

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By: Margaret A. Hamburg
Signature of authorized representative

Date: September 16, 2011

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
DHHS Food and Drug Administration

APPROVED AND ACCEPTED FOR THE AGRICULTURAL MARKETING SERVICE

By: David R. Shipman
Signature of authorized representative

Date: September 22, 2011

David R. Shipman
Acting Administrator
USDA Agricultural Marketing Service

APPROVED AND ACCEPTED FOR THE FOOD AND NUTRITION SERVICE

By: _____
Signature of authorized representative

Date: Sept 21, 2011

Audrey Rowe
Administrator
USDA Food and Nutrition Service

APPROVED AND ACCEPTED FOR THE FARM SERVICE AGENCY

By: Bruce Nelson Date: 9/29/11
Signature of authorized representative

Bruce Nelson
Administrator
USDA Farm Service Agency

APPENDIX A

List of Foods Procured by USDA Agencies

Additions and deletions to the list of USDA Foods purchased for use in USDA domestic nutrition assistance programs may be modified at any time without notice and shall not require a modification to this agreement. Please refer to the Agency website for a complete list of available products.

A. Agricultural Marketing Service, Group A Commodities

The AMS, Poultry Programs, Commodity Procurement Division acts as the purchasing agent for the following perishable foods that are distributed through FNS administered programs.

Commodity Procurement Division
Telephone: 202/720-4517
http://www.ams.usda.gov/AMSv1.0/CommodityPurchasing

Almonds
Canned and frozen apples, including juice
Canned and frozen apricots
Canned and frozen asparagus
Canned and dry beans
Canned and frozen green beans
Frozen blackberries
Dried and frozen blueberries
Canned, fresh and frozen carrots
Canned, frozen and dried cherries, including cherry/apple juice
Canned and frozen corn
Bottled corn syrup
Canned, frozen and dried cranberry products, including cranberry/apple juice
Dried dates
Dried fruit nut mix
Dried figs
Canned grape juice
Canned grapefruit juice
Canned mixed fruit
Canned mixed vegetables
Fresh oranges, including canned and concentrated orange juice
Canned and frozen peaches
Canned and fresh pears
Canned and frozen peas

Dried and canned plums
Canned, dehydrated, fresh and frozen potatoes
Canned pumpkin
Dried raisins
Frozen raspberries
Canned spinach
Frozen strawberries
Canned, fresh and frozen sweet potatoes
Canned and fresh tomato products, including juice
Canned vegetable soup
Walnuts
Fresh, frozen, cooked and canned beef products
Frozen, cooked and canned pork products
Frozen and canned bison products
Canned, frozen and pouch salmon products
Canned and pouch tuna products
Frozen and cooked catfish products
Frozen lamb products
Fresh, frozen and canned chicken products
Fresh, frozen and canned turkey products
Frozen geese products
Frozen egg products
Fresh Shell eggs
Bulk whole eggs
Dried egg mix

B. Farm Service Agency, Group B Commodities
The Domestic Procurement Division
Telephone: 816-926-6124
http://www.fsa.usda.gov/FSA/webapp?area=home&subject=coop&topic=pas

Bakery Flour
Bakery Mix
Corn Products
Crackers
Fortified Ready-to-Eat Cereal
Instant Rice Cereal
Processed Cereals
Macaroni & Cheese
Pasta Products
Wheat Flour
Peanut Products
Sunflower Seed Products
Rice Products
Vegetable Oil Products
Bulk Cheddar Cheese
Mozzarella Cheese
Process Cheese
Evaporated Milk
Infant Formula
Ultra High Temperature Milk
Instant Nonfat Dry Milk

APPENDIX B

Process for Information Sharing

While recognizing that the overall purpose of this MOU is to facilitate information sharing, pursuant to Section 4 of this MOU, 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. Nothing in the process described below changes Section 4.

When, under the current MOU, staff at the FDA or the appropriate USDA agency 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 requested 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-AMS-FSA-FNS Memorandum of Understanding. We agree not to disclose any shared information in any manner 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-AMS-FSA-FNS 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 manner 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Office of the Director (OD), National Institutes of Health.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, OD has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

DATES: Comments must be submitted within 30 days after publication in FR.

ADDRESSES: Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by Email to *OIRA_submission@omb.eop.gov,* or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Mikia P. Currie, Program Analyst, Office of policy for Extramural Research Administration, 6705 Rockledge Drive Suite 350, Bethesda, MD 20892–7974, or Email your request, including your address to *curriem@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

Abstract: The information collection activity will garner qualitative customer