health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

The Council meeting is being held in conjunction with the East Coast Migrant Stream Forum sponsored by the North Carolina Community Health Center Association, which is being held in Charleston, South Carolina, October 21–23, 2010.

Agenda items are subject to change as priorities indicate.

For Further Information Contact: Marcia Gomez, M.D., Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; telephone (301) 594–4897.

Dated: August 5, 2010.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2010–19751 Filed 8–10–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee I—Career Development, NCI–I Career Development.

Date: September 21, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Sergei Radaev, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd, Rm 8113, Bethesda, Md 20892, 301–435–5655, *sradaev@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 5, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19787 Filed 8–10–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—National Biosurveillance Advisory Subcommittee (NBAS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the CDC announces the following meeting of aforementioned subcommittee:

Time and Date: 8 a.m.–3:30 p.m., August 24, 2010.

Place: Emory Conference Center Hotel, 1615 Clifton Road, N.E., Atlanta, GA 30329.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people. The public is welcome to participate during the public comment periods. The public comment periods are tentatively scheduled for 10 a.m.–10:05 a.m. and 3:25 p.m.–3:30 p.m.

Purpose: As a subcommittee to the CDC's ACD, the NBAS will provide counsel to the CDC and the Federal government through the ACD regarding a broad range of human health surveillance issues arising from the development and implementation of a roadmap for the human health component of a national biosurveillance system.

Matters to be Discussed: Agenda items will include establishing task force action plans for developing recommendations and guidance in order to expand and strengthen the national portfolio of activities in biosurveillance practice and scientific assessment.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Pamela Diaz, M.D., Designated Federal Officer, ACD,CDC—NBAS, 1600 Clifton Road, NE., M/S E–33, Atlanta, GA 30333. Telephone: (770) 488–8806. E-mail: *pdiaz@cdc.gov.* For security reasons, members of the public interested in attending the meeting should contact Mark Byers, Telephone: (770) 488–8619, E-mail: *mbyers@cdc.gov.* The deadline for notification of attendance is August 13, 2010.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 4, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–19783 Filed 8–10–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0004]
[FDA 225–10–0010]

Memorandum of Understanding Between United States Food and Drug Administration and the Centers for Medicare and Medicaid Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Centers for Medicare and Medicaid Services (CMS), both part of the U.S. Department of Health and Human Services. The purpose of the MOU is to promote collaboration and enhance knowledge of efficiency by providing for the sharing of information and expertise between the Federal partners. The goals of the collaboration are to explore ways to further enhance information sharing efforts through more efficient and robust inter-agency activities; promote efficient utilization of tools and expertise for product analysis, validation, and risk identification; and build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics, and medical devices.

DATES: The agreement became effective June 25, 2010.

FOR FURTHER INFORMATION CONTACT: David H. Dorsey, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4222, Silver Spring, MD 20993, 301–796–4800.

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: August 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MOU Number 225-10-0010

MEMORANDUM OF UNDERSTANDING

BETWEEN

UNITED STATES FOOD AND DRUG ADMINISTRATION

AND

CENTERS FOR MEDICARE & MEDICAID SERVICES

1. Preamble

The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS), both as part of the Department of Health and Human Services, and hereinafter also referred to as "Federal partners," agree to work together to promote initiatives related to the review and use of FDA-regulated drugs, biologics, medical devices, and foods, including dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act (see 21 U.S.C. 321) and the Public Health Service Act. (See 42 U.S.C. 262).

2. Purpose and Goals

The purpose of the MOU is to promote collaboration and enhance knowledge and efficiency by providing for the sharing of information and expertise between the Federal partners. The goals of the collaboration are to explore ways to:

a. Further enhance information sharing efforts through more efficient and robust inter-agency activities.

b. Promote efficient utilization of tools and expertise for product analysis, validation and risk identification.

c. Build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics and medical devices.

3. Substance of the Agreement - Program Areas and Responsibilities/Activities

a. Each Federal partner will establish a principal point of contact to facilitate the actions carried out under this MOU.

b. FDA and CMS agree to attend an initial meeting to establish the specific procedures and safeguards necessary to implement this MOU. The initial meeting will take place within 30 days of signing and approval of this MOU. Periodic meetings will be scheduled thereafter on an as needed basis. FDA and CMS agree not to share information under this MOU unless, and until, adequate procedures and safeguards are established and implemented by each Federal partner.

c. FDA and CMS agree that each initial request for information will be made by and transmitted to the Agency principal point of contacts designated according to Section 3.a. of this MOU. Subsequent communications pertaining to that issue may occur between other staff as outlined in the initial request for information.

d. FDA and CMS agree that 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 3.b., or to limit the scope of information and expertise sharing in response to a particular request. A decision not to share information in response to a specific request may be based on several factors, including, for example, the amount of resources necessary to fulfill the request, the reasonableness of the request, the responding Federal partner's priorities, or legal restrictions. In the event that Federal partners can not reach consensus on a decision to share or not share information, the issue will be referred to the FDA Deputy Commissioner and CMS Administrator for a final decision.

e. FDA and CMS agree to establish reasonable timelines for responding to information requests and to refer instances of delays to the Agency point of contact for resolution.

f. FDA and CMS recognize that the following types of information transmitted between them in any medium and from any source must be protected from unauthorized disclosure: (1) trade secret and other confidential commercial information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. § 1905), the Privacy Act (5 U.S.C. § 552a), the Freedom of Information Act (5 U.S.C. § 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

g. FDA and CMS agree to promptly notify the relevant Federal partner(s) of any actual or suspected unauthorized disclosure of information shared under this MOU.

4. General Provisions

a. Safeguarding & Limiting Access to Shared Information

The procedures established under Section 3.b. must include proper safeguards against unauthorized use and disclosure of the 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 used solely in accordance with 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], and their implementing regulations, as well as the HIPAA Privacy Rule [45 C.F.R. Parts 160 and 164]. FDA and CMS shall establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the information and to prevent unauthorized access to the information provided by the other Federal partner.

Access to the information shared under this MOU shall be restricted to authorized FDA and CMS 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. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information, and (3) the administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws.

If an agency that has received information under this MOU receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the originating 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 originating agency.

b. Restriction on Use of Information

All information provided by FDA or CMS shall be used solely for the purposes outlined in Section 2. If FDA or CMS wish to use the information provided by the other Federal agency under this MOU for any purpose other than those outlined above, the requesting agency shall make a written request to the other agency describing the additional purposes for which it seeks to use the information. If the agency receiving this request determines that the request to use the information provided hereunder is acceptable, it shall provide the requesting agency with written approval of the additional use of the information.

c. Effect on Existing Statutes and Regulations

FDA and CMS agree to take actions under this collaboration that are consistent with existing laws and regulations, and that nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by FDA and CMS including but not limited to: Title 42 of the United States Code, the Public Health Service Act, and the Federal Food, Drug, and Cosmetic Act. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on FDA or CMS that is additional to the mandates or requirements imposed on FDA or CMS by Federal statutes and regulations.

d. Resource Obligations

FDA and CMS will designate respective project managers to oversee the administration of, and adherence to, the content of this MOU. These project managers shall include one or more designated individuals from any of the following: FDA's Office of the Commissioner and CMS' Office of the Administrator; FDA's Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Center for Food Safety and Applied Nutrition, and Office of Regulatory Affairs; and CMS' Office of Clinical Standards and Quality and Centers for Medicare Management.

FDA and CMS will make reasonable efforts to provide the necessary staff to implement this MOU in an efficient and effective manner.

5. Assessment Mechanisms

FDA and CMS staff involved in implementing the MOU will provide regular and consistent oversight and reevaluation of all terms and conditions contained herein.

6. Terms, Termination or Modification

This MOU becomes effective upon the signature of both the FDA and CMS and will remain in effect for 5 years, unless otherwise terminated. This agreement may be modified by unanimous consent or terminated by any party upon 60 days written notice. This agreement may be modified by consent of both Federal partners or terminated by any party immediately upon written notice in the event that a Federal statute is enacted or a regulation is issued by a Federal partner that materially affects this MOU.

MOU Number 225-10-0010

7. **Principal Point of Contacts**

David H. Dorsey, J.D.
Acting Deputy Commissioner for Policy, Planning and Budget
Office of Policy, Planning and Budget
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue, WO-1
Silver Spring, MD 20993
301 -796-4800

Barry M. Straube, M.D.
CMS Chief Medical Officer
Director. Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard, S3-02-01
Baltimore, MD 21244
410-786-6841

APPROVED AND ACCEPTED FOR CENTERS FOR MEDICARE & MEDICAID SERVICES

By: Marilyn Tavenner
Marilyn Tavenner
Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services

Date: 6-18-2010

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By: Margaret A. Hamburg
Margaret A. Hamburg, M.D.

Commissioner of Food and Drugs

Date: 6-25-2010

MOU Number 225-10-0010

APPENDIX A

PROCESS FOR INFORMATION SHARING

Pursuant to Section 3.d of the Memorandum Of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) 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 3.b., or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section 3.d.

When, under the current MOU, staff at the FDA or CMS 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 2010 FDA-CMS Memorandum of Understanding to Share Information. 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 2010 FDA-CMS Memorandum of Understanding to Share Information, 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.

[FR Doc. 2010–19772 Filed 8–10–10; 8:45 am]
BILLING CODE 4160–01–C