For Further Information Contact: Demetria Gardner, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., (E–05), Atlanta, Georgia 30333, telephone 404/639–8836, fax 404/639–6258.

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 the CDC and ATSDR.

Elaine L. Baker,

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

[FR Doc. E7–1490 Filed 1–30–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 71 FR 69211, dated November 30, 2006) is amended to reflect the establishment of the Extramural Research Program Office within the National Center for Injury Prevention and Control, coordinating Center for Environmental Health and Injury Prevention.

Section C–B, Organization and Functions, is hereby amended as follows: After the functional statement for the *Office of Communication Resources (CTC14), Office of the Director (CTC1), National Center for Injury Prevention and Control (CTC),* insert the following:

Extramural Research Program Office (CTC16). The Extramural Research Program Office (ERPO) plans, develops, coordinates, and evaluates extramural research activities in cooperation with centers, divisions, and offices within the Coordinating Center for Environmental Health and Injury Prevention. In carrying out its mission, the ERPO: (1) Directs the Extramural research program by planning, coordinating, developing, implementing, monitoring, and evaluating extramural research that is designed to address center priorities; (2) participates with divisions and offices within the center to establish research priorities for the center; (3) provides scientific leadership in the areas of extramural research supported by the center; (4) promotes and prepares initiatives to stimulate extramural research in relevant priority areas; (5) coordinates and conducts in-depth external peer review and secondary program relevance review of extramural research applications by use of consultant expert panels; (6) makes recommendations to the center director on award selections and staff members serve as the program officials in conjunction with CDC grants management and policy officials to implement and monitor the scientific, technical, and administrative aspects of awards; (7) facilitates scientific collaborations between external and internal investigators; (8) disseminates and evaluates extramural research progress, findings, and impact; and (9) assists the Office of Chief Science Officer, CDC, in developing extramural research policies and oversees the implementation of those policies within the center.

Dated: January 9, 2007.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 07–417 Filed 1–30–07; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0136]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Interstate Shellfish Dealers Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Interstate Shellfish Dealers Certificate'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 13, 2006 (71 FR 60545), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0021. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1549 Filed 1–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–4300]

Memorandum of Understanding Between the United States Food and Drug Administration and the Veterans Health Administration

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 Veterans Health Administration. The purpose of this MOU is to enhance knowledge and efficiency by providing for the sharing of information and expertise related to the review and use of FDA-regulated drugs, biologics, and medical devices between the two agencies. The goals of the collaboration are to explore ways to: Further enhance information sharing efforts through more efficient and robust interagency activities; promote efficient utilization of tools and expertise for product risk identification, validation, and analysis; and build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, and utilization of drugs, biologics, and medical devices.

DATES: The agreement became effective January 23, 2007.

FOR FURTHER INFORMATION CONTACT: Jeffrey Shuren, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

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: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

FDA # 225-07-4300

MEMORANDUM OF UNDERSTANDING BETWEEN THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THE VETERANS HEALTH ADMINISTRATION

1. A MEMORANDUM OF UNDERSTANDING (MOU) TO SHARE INFORMATION

The Food and Drug Administration (FDA) as part of the Department of Health and Human Services and the Veterans Health Administration (VHA) as part of the Department of Veterans Affairs, both United States Federal Government entities and hereinafter also referred to as "Federal partners", agree to share information related to the review and use of FDA-regulated drugs, biologics, and medical devices, 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. MOU PURPOSE AND GOALS

The purpose of the MOU is to 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 risk identification, validation and analysis.

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

3. MOU PROGRAM AREAS AND RESPONSIBILITIES/ACTIVITIES

a. Each Federal partner will establish a single Agency liaison to facilitate the actions carried out under this MOU. Ideally, the liaisons will be organizationally aligned under the Office of the FDA Commissioner and the VHA Office of the Under Secretary for Health.

b. VHA and FDA 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 a quarterly basis. VHA and FDA agree not to share information under this MOU unless, and until, adequate procedures and safeguards agreed upon by both Federal partners are established and implemented.

c. VHA and FDA agree that the initial request for information will be made by and transmitted to the Agency liaisons designated according to Section 3.a. of this MOU. Subsequent communications pertaining to that issue may occur between other staff as approved by the liaisons.

d. FDA and VHA agree that either 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 both partners can not reach consensus on a decision to share or not share information, the issue will be referred to the FDA Deputy Commissioner for Operations and the VHA Under Secretary for Health for a final decision.

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

f. FDA and VHA recognize that information transmitted between them in any medium and from any source, that contains any of the following types of information must be protected from unauthorized disclosure: (1) confidential commercial information, such as the 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., 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), 38 U.S.C. § 5701, 38 U.S.C. § 5705, 38 U.S.C. § 7332, 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 VHA agree to promptly notify the other Federal partner of any actual or suspected unauthorized disclosure of information shared under this MOU.

4. 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]. The VHA and FDA 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 VHA 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. VHA contractors, their subcontractors and agents requiring the access to the information shared under this agreement will be required to sign a business associate agreement.

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 information-sharing 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.

5. RESTRICTION ON USE OF INFORMATION

All information provided by the Federal partners shall be used solely for the purposes outlined in Section 2. If either Federal partner wishes to use the information provided by the other Federal partner 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.

6. EFFECT OF MOU ON EXISTING STATUTES AND REGULATIONS

FDA and VHA 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 VHA and FDA, including but not limited to: title 38 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 either FDA or VHA that is additional to the mandates or requirements imposed on VHA or FDA by Federal statutes and regulations.

FDA # 225-07-4300

7. PLANNED RESOURCES FOR MOU

a. FDA and VHA will designate respective liaisons to oversee the administration of, and adherence to, the content of this MOU. These liaisons shall include one or more designated individuals from FDA's Office of the Commissioner and VHA's Office of the Under Secretary for Health; from FDA's CDER, CDRH and CBER, and VHA's Pharmacy Benefits Management Strategic Healthcare Group.

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

8. ASSESSMENT MECHANISMS

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

9. TERM OF MOU

This MOU becomes effective upon the signature of both Federal partners and the implementation of the procedures and safeguards agreed upon by both Federal partners described in Section 3 and will remain in effect for 3 years from that date. This agreement may be modified by mutual consent or terminated by either party upon 60 days written notice. This agreement may be modified by mutual consent or terminated by either party immediately upon written notice in the event that a Federal statute is enacted or regulations are issued by either Federal partner that materially affect this MOU.

10. SIGNATURES OF VHA AND FDA APPROVING OFFICIALS

Andrew C. von Eschenbach

Andrew C. von Eschenbach, MD
Commissioner of Food and Drugs
Department of Health and Human Services

1/23/2007
Date

Michael J. Kussman

Michael J. Kussman, MD, MS, MACP
Acting Under Secretary for Health
Department of Veterans Affairs

16 January 2007
Date

[FR Doc. 07–421 Filed 1–30–07; 8:45 am]
BILLING CODE 4160–01–C