System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

**V. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: December 11, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–29953 Filed 12–16–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0043]**
**[FDA No. 225–08–8003]**

### Memorandum of Understanding Between the Office of the Assistant Secretary of Defense (Health Affairs), the Veterans Health Administration, and the U.S. Food and Drug 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 the Office of the Assistant Secretary of Defense (Health Affairs), the Veterans Health Administration, and the U.S. Food and Drug Administration. 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: 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, as well as the safety and utilization of foods. The MOU is available on FDA's Web site at *www.fda.gov/oc/mous/domestic/domesticmous.htm*.

**DATES:** The agreement became effective November 25, 2008.

**FOR FURTHER INFORMATION CONTACT:** Erik Mettler, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4324, Silver Spring, MD 20993, 301–796–4830.

**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: December 11, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

FDA Record No. 225-08-8003

**MEMORANDUM OF UNDERSTANDING**

**BETWEEN**

**THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS),**

**THE VETERANS HEALTH ADMINISTRATION**

**AND**

**THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

## 1. Preamble

The Food and Drug Administration (FDA) as part of the Department of Health and Human Services, the Office of the Assistant Secretary of Defense (Health Affairs) as part of the Department of Defense (DoD), and the Veterans Health Administration (VHA), as part of the Department of Veterans Affairs, all United States Federal Government entities and hereinafter also referred to as "Federal partners", agree to work together to promote safety 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 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, as well as the safety and utilization of foods.

## 3. Substance of the Agreement - 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, the DoD Office of the Assistant Secretary of Defense (Health Affairs), and the VHA Office of the Under Secretary for Health.

b. DoD, 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. DoD, VHA and FDA agree not to share information under this MOU unless, and until, adequate procedures and safeguards agreed upon by each Federal partner are established and implemented.

c. VHA, DoD, and FDA agree that each 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, VHA, and DoD 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, the DoD Assistant Secretary of Defense (Health Affairs), and/or the VHA Under Secretary for Health for a final decision.

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

f. FDA, DoD, 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), 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, VHA, and DoD 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]. DoD, 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, DoD, 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. DoD and VHA contractors, their subcontractors and agents who are determined to be business associates of the DoD or VHA and require access to any protected health 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 information-sharing agency.

**B. Restriction on Use of Information**

All information provided by the Federal partners shall be used solely for the purposes outlined in Section 2. If a Federal partner wishes to use the information provided by one of the other Federal partners 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, DoD, 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 DoD, VHA, and FDA, including but not limited to: title 10 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, VHA, or DoD that is additional to the mandates or requirements imposed on DoD, FDA, or VHA by Federal statutes and regulations.

**D. Resource Obligations:**

FDA, VHA, and DoD 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, DoD's Office of the Assistant Secretary of

Defense (Health Affairs), and VHA's Office of the Under Secretary for Health; from FDA's Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, and Center for Food Safety and Applied Nutrition, DoD's TRICARE Management Activity, Pharmaceutical Operations Directorate, and VHA's Pharmacy Benefits Management Services.

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

## 5. Assessment Mechanisms

FDA, VHA, and DoD 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 all three Federal partners and the implementation of the procedures and safeguards agreed upon by the Federal partners described in Section 3. This agreement may be modified by unanimous consent or terminated by any party upon 60 days written notice. This agreement may be modified by unanimous consent 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.

## 7. Liaison Officers

Jeffrey Shuren
Associate Commissioner for Policy and Planning
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20257
301 -827-3360

RADM Thomas J. McGinnis
Chief, Pharmaceutical Operations Directorate
TRICARE Management Activity
Five Skyline Place, Suite 8 10
5111 Leesburg Pike
Falls Church, Virginia 22041-3 206
703-681-2890

Michael Valentino
Chief Consultant
Pharmacy Benefits Management Services
810 Vermont Avenue NW
Washington, DC 20420
202-461-7360

FDA Record No. 225-08-8003

**APPROVED AND ACCEPTED FOR:**

**THE FOOD AND DRUG ADMINISTRATION**

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

7/23/08
**Date**

**THE DEPARTMENT OF DEFENSE**

**S. Ward Casscells, MD**
**Assistant Secretary of Defense (Health Affairs)**
**Department of Defense**

NOV 25 2008
**Date**

**THE VETERANS HEALTH ADMINISTRATION**

Michael J. Kussman

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

9/8/08
**Date**

FDA Record No. 225-08-8003

## 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), the Veterans Health Administration (VHA), and the Department of Defense (DoD), 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 MOUs, staff at the FDA, the VHA, or the DoD 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 2008 FDA-VHA-DoD Memorandum of Understanding to Share Information. We agree not to disclose any shared information in any manner without your written permission." 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 2008 FDA, VHA, DoD 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 outside of the parties to this MOU." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

# Protocol for Information Sharing Under MOU 225-08-8003

**Between**

**Veterans Health Administration (VHA) and the Food and Drug Administration (FDA)**

**Surveillance for Unexpected Adverse Events and Product Problems Associated with the Use of Cardiac Devices**

## Introduction:

The Veterans Health Administration (VHA) has extensive methods for ensuring quality and safety in the provision of care. For instance, the Cardiovascular Assessment Reporting and Tracking system (CART) has been implemented as a national solution for managing procedure reporting in the cardiac catheterization laboratory. All VHA facilities enter data in the same standardized fashion for pre-procedure notes and for diagnostic catheterization, interventions, and other procedure reports. The output from CART is an appropriate note written into the patient's electronic medical record. In addition, computable data points and some free-text are stored in a national database (CART Data Repository). Included among this is the opportunity to document any unexpected problems encountered with equipment or devices used in the course of the procedure.

The Food and Drug Administration (FDA) is charged with ensuring patient safety, which includes oversight of biomedical devices. Despite rigorous testing of new devices prior to general availability, problems and complications do not always manifest during the pivotal clinical trials. While the MedWatch program is in place to communicate device problems directly from clinicians to the FDA, it is inconsistently used and is generally limited to the more egregious events. It is therefore important to engage in more sensitive systems for surveillance as devices migrate into use in broader practice, and thus other sources of information are needed to better characterize device performance in the post market period.

Both VHA and FDA concur that the CART process could serve as an important mechanism to identify problem(s) with cardiovascular devices early.

## Purpose:

It is the intention of VHA and FDA to bi-directionally share data regarding problems or issues with cardiac devices that might serve to identify potential patient safety issues early. This protocol will establish terms governing that exchange of data, specifically regarding performance of cardiovascular devices.

**Agreement:**

**VHA will:**

1. Identify a liaison within the CART management group to serve as the point-of-contact for the FDA. (CART point of contact)
2. Review CART data fields for indications of unexpected problem(s) with cardiac devices on a regular basis.
3. Notify FDA of any signal from CART suggesting there might be a problem with a particular device.
4. Review CART reports for indications of problems with a specific device at the request of FDA.

**VHA will not:**

1. Reveal patient specific identifiers to the FDA.
2. Release any data attributable to the FDA to any other entity without written permission from the FDA.

**FDA will:**

1. Review CART device reports to determine if there are other data sources suggesting a similar problem, and notify VHA of those findings.
2. Notify VHA if there is indication of device failures originating from other sources so VHA can survey its database looking specifically for similar issues within VA's system.

**FDA will not:**

1. Release any data that is attributable to VHA to any other entity without written permission from VHA.

**Data Exchange Levels:**

Data will be shared between the CART program staff and the FDA in three step-wise levels of increasing detail. All data exchange will begin with Level I, defined below, and proceed consecutively to Level II or III, as warranted by patient safety or device surveillance concerns.

Level I data exchange represents a simple accounting of the text comments provided in the CART unexpected device complications field. Basic information regarding the procedure and device is provided, de-identified to the hospital level. Summary reports will be shared and discussed with FDA on a monthly basis. No protected health information (PHI) is included.

The information provided may not be disclosed or used for any purpose other than as outlined in this Agreement except and unless specific approval is obtained. All data and information provided by VA and FDA shall be used solely for the purposes outlined in the Agreement. If FDA wishes to use the data and information provided by VA under this Agreement for any purpose other than those outlined above, FDA shall make a written request to VA describing the additional purposes for which it seeks to use the data. If VA determines that the FDA's request to use the data and information provided hereunder is acceptable, VA shall provide FDA with written approval of the additional use of the data.

**Agreement Terms:**

The ~~MOU~~ protocol will cover the period from the date of execution through fiscal year 2010. Any changes to this agreement must be mutually agreed upon in writing by both parties. The ~~MOU~~ protocol can be extended based on mutual agreement of both parties. Either FDA or VHA can end the agreement at the end of any fiscal year, should the needs and requirements of either organization not be met. Should the agreement end, all data must be returned to its source of origin or destroyed.

**Execution:**

Executed on this 4 day of December 2008.

Between

Michael J. Kussman

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health
Veterans Health Administration

Daniel G. Schultz, MD
Director, FDA Center for Devices and Radiological Health
Food and Drug Administration

[FR Doc. E8–29952 Filed 12–16–08; 8:45 am]
**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; The Effectiveness of the NIH Curriculum Supplements Programs and Career Resources

*Summary:* Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, Office of Science Policy, Office of Science Education, National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 23, 2008 (Volume 73, Number 185, page 54840) and allowed 60-days for public comment. One comment was received. The purpose of this notice is to allow 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

*Proposed Collection Title:* The Effectiveness of the NIH Curriculum Supplements Programs and Career Resources.

*Information Collection Request:* Reinstatement.

*Need and Use of Information Collection:* The survey will attempt to assess customer demographics and their satisfaction with the NIH curriculum supplements in presenting science in a more engaging and interactive way. The supplements help K–12 educators teach science by featuring the latest NIH research and utilized research-based instructional methods. A typical supplement contains two weeks of student activities on the science behind a health topic, such as cancer, sleep or obesity. Web-based simulations, animations and experiments enhance the ''pencil and paper'' activities. In addition to developing and distributing the supplements, OSE conducts professional workshops to help teachers successfully implement these lessons with their students. Since January 2000, over 6,000 teachers have attended an OSE workshop. OSE also develops a series of videos, *Women Are Scientists,* that aim to excite middle school students on careers in the health sciences. Assessing the effectiveness of the NIH curriculum supplements, teacher workshops, and career resources is critical to determining if OSE is successfully fulfilling its mission. OSE has the database infrastructure in place to easily collect data from supplement and career video requesters and workshop attendees. At present, we do not have clearance to contact our customers to determine how NIH resources are meeting their educational needs.

**Burden Table**

| Type of respondent: Survey title | Number of respondents | Frequency of response | Average time per response (hours) | Hour burden per year (hours) |
|---|---|---|---|---|
| Supplement requestor | 16,000 | 1 | 0.17 | 910 |
| Career video requestor | 1,500 | 1 | 0.17 | 85 |
| Workshop Teacher: initial survey | 2,000 | 1 | 0.17 | 117 |
| Workshop Teacher: in-depth survey | 200 | 1 | 0.5 | 34 |
| Totals | 19,700 | [a] | [a] | 1,146 |

[a] N/A.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) ways to enhance the quality, utility, and clarity of the information to be collected; and (3) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. David Vannier, National Institutes of Health, Office of Science Education, 6100 Executive Boulevard, Suite 3E01, Bethesda, MD 20892, or call 301–496–8741, or e-mail your request including your address to *vannierd@od.nih.gov.*

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: December 4, 2008.

**David Vannier,**

*Office of Science Education, National Institutes of Health.*

[FR Doc. E8–29815 Filed 12–16–08; 8:45 am]
**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); notice is hereby given of the following meetings.

The meetings 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.