to CMS. The burden associated with this requirement is currently approved under OMB control number 0938–0880 with an expiration date of November 20, 2010.

**Authority:** Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173. (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: January 11, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 08–511 Filed 2–1–08; 10:00 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0079]**

### Guidance for Industry: Fish and Fisheries Products Hazards and Controls Guidance Third Edition June 2001: Letter to Seafood Processors that Purchase Grouper, Amberjack, and Related Predatory Reef Species Captured in the Northern Gulf of Mexico

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001: Letter to Seafood Processors that Purchase Grouper, Amberjack and Related Predatory Reef Species Captured in the Northern Gulf of Mexico.'' The guidance sets forth the agency's recommendations for ensuring the safety of grouper, amberjack, and related predatory reef species captured in the northern Gulf of Mexico with respect to ciguatera fish poisoning (CFP). The guidance is in response to recent cases of CFP that have occurred in the United States.

**DATES:** This guidance is final February 6, 2008. Submit written or electronic comments on the guidance document at any time.

**ADDRESSES:** Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 301–436–2651. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Byron Truglio, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1420.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a guidance document entitled ''Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001: Letter to Seafood Processors that Purchase Grouper, Amberjack and Related Predatory Reef Species Captured in the Northern Gulf of Mexico.'' The purpose of the document is to revise guidance provided to industry for processing potentially ciguatoxic fish species captured in the northern Gulf of Mexico which are subject to the provisions of the Hazard Analysis and Critical Control Point regulation for seafood (21 CFR part 123) (the seafood HACCP regulation). This guidance is in response to recent CFP outbreaks that have been traced to fish captured in an area in the United States where ciguatera was previously extremely rare. CFP is caused by consumption of fish that have eaten toxic marine algae directly or that have eaten other toxin-contaminated fish. CFP can result in gastrointestinal, cardiovascular, and neurological symptoms. In severe cases, recurring neurological symptoms can persist for months to years.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g) (2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the recent cases of CFP. The guidance represents the agency's current thinking on CFP from fish in the Northern Gulf of Mexico. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. This guidance modifies our previous guidance on this subject (See ''Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001'' *http://www.cfsan.fda.gov/guidance.html*). The recommendations in this guidance only pertain to grouper, amberjack, and related predatory reef species associated with CFP that have been captured in the Northern Gulf of Mexico. This guidance does not pertain to other species of fish that have not been associated with CFP.

#### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

#### III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: January 31, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 08–537 Filed 2–1–08; 4:38 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[FDA No. 225–07–8007]**

### Memorandum of Understanding Between the Food and Drug Administration and the National Institutes of Health

**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 National Institutes of Health (NIH). This MOU establishes the terms of collaboration between the two Federal agencies to develop a unified Federal approach to adverse event (AE) reporting. Specifically, FDA and NIH will collaborate in development of a project that will result in a web-based method for consumers, health professionals, investigators, sponsors, and other parties to electronically submit AE reports. The project includes the development of at least two products: (1) A Rational Questionnaire, an interactive help system that will assist reporters of information in determining what specific data need to be submitted and to whom, and (2) a prototype to test the feasibility of a central, Federal web-based portal to provide direct, seamless, online submission of adverse event reports to appropriate agencies.

**DATES:** The agreement became effective September 27, 2007.

**FOR FURTHER INFORMATION CONTACT:** Daryl Allis, OC/Office of Critical Path Programs, Food and Drug Administration, 5600 Fishers Lane (HF–18), Rockville, MD 20785, 301–827–7868.

**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 28, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

**BILLING CODE 4160–01–S**

FDA No. 225-07-8007

# MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION AND NATIONAL INSTITUTES OF HEALTH

## I. PARTIES

This Agreement is between the U.S. Department of Health and Human Services, U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services, National Institutes of Health (NIH), collectively, "the Parties."

## II. OVERVIEW

### A. Introduction

The FDA and the NIH both recognize the need for a unified federal approach to adverse event (AE) reporting. Such a harmonized approach will facilitate and streamline submission of both pre- and post-market AE reports while improving data quality and analysis, as well as improving human subject protections. The FDA and NIH began discussions to determine the feasibility of combining efforts to develop web-based portals for AE reporting in order to leverage these efforts and develop a single product that could be used by both Agencies to improve report quality, lower costs, and reduce delivery time. This Agreement memorializes the joint efforts that will be undertaken to effectuate this goal.

### B. Background

The FDA, as part of its ongoing work in improving the nation's safety surveillance system, has commenced work on a project, titled MedWatch$^{Plus}$, to create an Agency-wide portal through which adverse event, consumer complaint, and product problem reports are received and processed to make the information available to adverse event analysis systems. The FDA has invested resources over a period of three years to achieve American National Standards Institute (ANSI) approval of a technical standard for exchanging adverse event data, called the "HL7 – Individual Case Safety Report (ICSR)." The use of the HL7 ICSR standard as part of the MedWatch$^{Plus}$ project enables FDA to implement the standard for all FDA-regulated products (e.g., animal and human food/feed (medicated and unmedicated), cosmetics, dietary supplements, animal and human drugs, biologics, devices, combination products, pet treats, vaccines, etc.). Currently, FDA's adverse event (AE) data collection needs in MedWatch$^{Plus}$ are for adverse events associated with the use of marketed products. FDA expects to receive electronic submission of AE's in clinical trials in the future.

The NIH, through extensive consultation with more than 300 nationally recognized leaders in academia, industry, government, and the public, identified harmonization of clinical research requirements as the highest priority concern of investigators, IRBs, and others involved in clinical research. Furthermore, these stakeholders urged that the NIH assume as its first priority streamlining the highly diverse Federal requirements for the reporting of adverse events that occur during clinical trials. These requirements are imposed by the FDA, NIH, and other agencies of the Federal government.

At present, in reporting a given adverse event, an investigator typically has to submit separate reports to multiple agencies, using different forms, vocabularies, severity criteria, and reporting timeframes. Oversight bodies and agencies receiving this information are often faced with tremendous volumes of data reported in idiosyncratic ways, which often frustrates efforts to conduct meaningful aggregations and analyses of data, or to cull from reports information key to important safety concerns.

To address this problem, the NIH Director, along with the Director of the HHS Office of Human Research Protections (OHRP), established the Federal Adverse Event Task Force (FAET) as a collaborative effort among the FDA, the NIH, the OHRP, the Centers for Disease Control and Prevention, the Department of Veterans Affairs, the Department of Defense, and the Agency for Healthcare Research and Quality, collectively, the "FAET Agencies." Chaired and staffed by the NIH's CRpac Program, the FAET is charged with proposing specific means for promoting harmonized requirements and processes for reporting adverse events in clinical research to the relevant federal agencies.

To fulfill the adverse event reporting requirements and needs of the FAET Agencies, the FAET proposed a consensus standard, for data elements of a Basal Adverse Event Report (BAER). The value of this accomplishment can only be realized if it is translated into reporting tools for investigators and agencies alike.

To this end, NIH plans to develop a Web-based portal whereby investigators would prepare a single report using a standard format (the BAER). Investigators, sponsors, clinicians, and consumers will be able to convey instantaneously one report – utilizing, to the extent possible, a universally accepted vocabulary and format - to all agencies with oversight for that particularly study.

C. Purpose

FDA and NIH are agreeing to collaborate on a project of mutual interest, specifically the development of a "Rational Questionnaire" and a prototype to test the feasibility of a central web-based portal for AE reporting (together, the "Project").

Put broadly, NIH and FDA aim to develop a Project that will result in a web-based method for consumers, health professionals, investigators, sponsors, and other parties to electronically submit AE reports. The Project is expected to create tools that will allow any user to submit adverse event information that corresponds to a wide range of forms already in use by many agencies (e.g. FDA 3500 and 3500A forms, and NIH and other

agency specific forms). The Project includes the development of at least two products: (1) a "Rational Questionnaire" – an interactive help system that will assist reporters of information in determining what specific data need to be submitted and to whom, and (2) a prototype to test the feasibility of a central, Federal web-based portal to provide direct, seamless, online submission of adverse event reports to appropriate agencies. The Rational Questionnaire is a reporting method component dependent on a web-based portal technical infrastructure. The central, Federal web-based portal prototype will provide an opportunity for NIH and FDA to better understand the technology infrastructure that may be needed to support a broader group of federal agencies.

This Agreement describes the terms of collaboration between FDA and NIH on the Project. Information will be shared and transparent, as permitted by law, so that the Parties can maximize efficient use of government resources to reach the Project goals.

D. Priorities and Funding

The Project is critical to the missions of both MedWatch$^{Plus}$ and the Federal Adverse Event Task Force. Successful completion of the project on schedule is vital. The FDA has a need to implement an electronic AE reporting system as soon as possible to satisfy several important mandates, including the requirement to receive mandatory AE reports for dietary supplements and to accommodate those reporters that prefer to submit electronically. FDA and NIH program needs will be prioritized as the Project and schedule for completion are developed.

The NIH has begun some work on the Project, including establishing contacts with technical experts and contractors to develop the two products described. The NIH will continue to serve as the primary point of contact for these contractors. The FDA will provide needed technical assistance but no funds will be transferred to NIH for these activities.

## III. RESPONSIBILITIES OF THE PARTIES

A. General

The Parties agree as follows:

1. They will jointly participate in the Project (to develop the Rational Questionnaire and portal prototype), including all phases of project management.

2. Project results will be available to both Parties to implement as they individually see fit, consistent with law.

3. The NIH, or its contractor(s) will provide explicit training to FDA personnel in the technical architecture and implementation of the prototype and application developed in the Project. The issue of ongoing maintenance will be resolved during the Project's development.

4. The Project will follow the HHS Enterprise Performance Lifecycle (EPLC) standard, as applicable, including for the production of all required documents.

5. The scope of the Project will be further, and mutually, defined and documented early in the Project.

6. A unified Requirements Matrix will be prepared, and appropriate FDA and NIH technical representatives will approve it.

7. Any software developed in the course of the Project will be available for both FDA and NIH to continue to use, develop and extend as they individually see fit, without limitation but subject to applicable law.

8. The Project documents will be maintained using agreed upon tools, with access granted to FDA and NIH staff as needed.
   a. FDA will be responsible for providing resources to maintain and manage the Project documents for the marketed products portion of the project
   b. NIH will be responsible for providing resources to maintain and manage the Project documents for the clinical trials portion of the project

9. The technology stack chosen to implement the Project will be approved in advance by the designated technical representatives from FDA and NIH.

10. The prototype Rational Questionnaire will be jointly developed and deliverable at a mutually agreed-upon date. The system will be developed in an iterative or

multi-phase fashion to enable FDA and NIH end-users to evaluate and refine the system during the course of development. The common components of the Questionnaire will be developed first and the marketed products and clinical trials components will be developed next in parallel, with different timelines, and with appropriate contributions to each.

11. The prototype portal in which the Rational Questionnaire will reside and by which the Parties can test the feasibility of generating adverse event reports through the Questionnaire for submission to Federal agencies will be jointly developed.

12. Before conclusion of this agreement, the Parties will discuss and decide if an Independent Validation and Verification test plan is needed in order to ensure that the Project meets all relevant specifications.

13. User Acceptance Testing (UAT) will be performed to ensure that the project meets requirements.

B. FDA

The FDA agrees to perform the following activities and provide the following resources in support of the project:

1. Collaborate and provide non-monetary resources for the project management of the common components of the Questionnaire and the marketed products components as well as the development of the portal prototype.
2. Provide useful, actionable requirements for the Project to satisfy FDA needs.
3. Participate in all Project management meetings as scheduled.
4. Collaborate in the design of the Project.
5. Provide FDA resources as needed to learn the technical architecture.
6. Provide FDA resources for implementation of the Project.

C. NIH

The NIH agrees to perform the following activities and provide the following resources in support of the project:

1. Collaborate and provide resources for the project management of the common components of the Questionnaire, and the clinical trial components as well as the development of the portal prototype.
2. Provide useful, actionable requirements for NIH needs.

3. Participate in all Project management meetings as scheduled.
4. Collaborate in the design of the Project.
5. Direct the contractor(s) in performance of their duties with input and agreement from FDA.
6. Provide NIH resources for implementation of this project.

## IV. PROJECT DURATION

The Project shall be considered finished when the key deliverables, the Rational Questionnaire and portal prototype are delivered and operational, but no later than three (3) months after the agreed-upon and scheduled completion date, which will be determined after work has begun.

## V. ISSUE RESOLUTION

The FDA and NIH program staff working on the Project are committed to productive and collaborative activities to achieve the important public health goals of the Project. Consistent with Federal law and agency practice, staff will work together to resolve any programmatic disputes and communicate within agency chain-of-command any differences or other concerns as necessary. It is expected that the first line of communication above the project staff will be FDA's Executive Sponsor of MedWatch$^{Plus}$ and NIH's Director for Science Policy, Office of the Director.

## VI. INFORMATION SHARING

As sister public health agencies within the Department of Health and Human Services, there are no legal prohibitions that preclude FDA or NIH from sharing with each other most agency records in the possession of either agency. Both agencies recognize and acknowledge, however, that it is essential that any confidential information that is shared between FDA and NIH must be protected from unauthorized use or disclosure. See, e.g., 21 USC. sec. 331(j); 18 U.S.C. section 1905; 21 C.F.R. Parts 20 and 21; 42 C.F.R. Parts 5 and 5b. Safeguards will be followed to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or predecisional agency records; and information protected for national security reasons.

FDA No. 225-07-8007

VII. PERIOD OF AGREEMENT AND MODIFICATION/TERMINATION

This Agreement will become effective when signed by all Parties. The Agreement will continue for not more than five years thereafter, unless amended by mutual agreement of the Parties, until the Project is completed. It is expected that the Project will take not more than two years to complete. Either party may terminate this Agreement by providing one hundred twenty (120) days written notice to the other party. Consistent with the expectation that no funds will be transferred between the Parties, each party shall be solely responsible for the payment of any expenses it has incurred in the event this Agreement is terminated before completion. This Agreement is subject to the availability of funds.

9/26/07 9/27/07

Janet Woodcock, M.D.
Deputy Commissioner, Chief Medical Officer
Office of the Commissioner
Food and Drug Administration
Department of Health and Human Services

Lana Skirboll, Ph.D.
Director for Science Policy
Office of the Director
National Institutes of Health
Department of Health and Human Services

[FR Doc. 08–496 Filed 2–5–08; 8:45 am]

**BILLING CODE 4160–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: The Division of Independent Review Grant Reviewer Recruitment Form (OMB No. 0915–0295): Extension**

HRSA's Division of Independent Review (DIR) is responsible for carrying out the independent and objective review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical, and complies with statutes, regulations, and policies. The review of applications is performed by experts knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the selection and assignment of expert grant reviewers to objective review committees, HRSA utilizes a Web-based data collection form to gather critical reviewer information. The *Grant Reviewer Recruitment Form* standardizes pertinent categories of reviewer information, such as: Areas of expertise, occupations, work settings; reviewer experience, and allows maximum use of drop-down menus to simplify the data collection process. The Web-based system also permits reviewers to update their information as needed. HRSA maintains a pool of approximately 5,500 individuals that have previously served on HRSA objective review committees.

The estimated annual burden is as follows:

| Grant recruitment form | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| New reviewer | 2,200 | 1 | 2,200 | 45 min. | 1,650 |
| Updating reviewer information | 250 | 1 | 250 | 20 min. | 84 |
| Total | 2,450 | ..... | 2,450 | ..... | 1,734 |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: January 30, 2008.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

[FR Doc. E8–2157 Filed 2–5–08; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center for Complementary & Alternative Medicine; Notice of Closed Meeting

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 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 Center for Complementary and Alternative Medicine Special Emphasis Panel, Clinical Sciences—member conflict (PA06–510).

*Date:* February 26, 2008.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavillion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Martin H. Goldrosen, PhD, Director, Office of Scientific Review, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Ste. 106, Bethesda, MD 20892–5475, (301) 451–6331, *goldrosm@mail.nih.gov*.

Dated: January 30, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08–507 Filed 2–5–08; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, February 20, 2008, 8 a.m. to February 21, 2008, 1 p.m., Courtyard Marriott, 2899 Jefferson Davis Highway, Arlington, VA, 22202 which was published in the **Federal Register** on January 28, 2008, FR08–298.

The meeting dates were changed from February 20–21, 2008 to February 21–22, 2008. The rest of the information remains the same. The meeting is closed to the public.

Dated: January 30, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08–504 Filed 2–5–08; 8:45 am]

**BILLING CODE 4140–01–M**