

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 10, 2008, from 8 a.m. to 4:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Karen F. Warburton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4238, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512396. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss general issues concerning the postmarket experience with various contact lens care products. The discussion will include recommendations on contact lens care product development topics such as preclinical testing and clinical performance measures, and labeling for contact lenses and lens care products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending

before the committee. Written submissions may be made to the contact person on or before June 5, 2008. Oral presentations from the public will be scheduled on June 10, 2008, between approximately 9:30 a.m. and 10 a.m. and between approximately 3:30 p.m. and 4 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 28, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 29, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management staff, 240-276-8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 15, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-11451 Filed 5-21-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA No. 225-08-2000]

Memorandum of Understanding With the U.S. Army Corps of Engineers, Mobile District

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 U.S. Army Corps of Engineers, Mobile District. This MOU establishes a mutual framework governing the respective responsibilities of the parties for the provision of health services through the Corps' Regional Occupational Health Center to FDA employees at the FDA Gulf Coast Seafood Laboratory. Goods and services the Corps may provide include, but are not limited to, physicals at age-appropriate intervals, referral of employees to private physicians, prevention programs related to health, and other related goods and services as meet the criteria and standards of the Public Health Service, immunizations for influenza and tetanus, and safety and environmental counseling.

DATES: The agreement became effective April 28, 2008.

FOR FURTHER INFORMATION CONTACT: Julia Pryor, Center for Food Safety and Nutrition, rm. 122 (HFS-400), Food and Drug Administration, P.O. Box 158, One Iberville Dr., Dauphin Island, AL 36528, 251-694-4479.

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: May 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

BILLING CODE 4160-01-S

MEMORANDUM OF AGREEMENT
BETWEEN
U.S. ARMY CORPS OF ENGINEERS, MOBILE DISTRICT
AND
U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
GULF COAST SEAFOOD LABORATORY

ARTICLE I - PURPOSE AND AUTHORITY

This Memorandum of Agreement (MOA) is entered into by and between the U.S. Army Corps of Engineers, Mobile District (Corps) and FDA/Gulf Coast Seafood Laboratory (the parties) for the purpose of establishing a mutual framework governing the respective responsibilities of the parties for the provision of health services through the Corps' Regional Occupational Health Center (ROHC). This MOA is entered into pursuant to the Economy in Government Act (31 U.S.C. § 1535).

ARTICLE II - SCOPE

Goods and services that the Corps may provide under this MOA include (1) upon request, annual physicals for employees 40 years of age or older; triennially for employees less than 40 years of age; (2) referral of employees to private physicians; (3) pre-employment and other examination; (4) prevention programs relating to health, and such other related goods or services as meet the criteria and standards of the Public Health Service, that are authorized and agreed upon in the future; (5) immunizations for influenza and tetanus as supplies are available; (6) safety and environmental counseling; and (7) ergonomic counseling and evaluation.

Nothing in this MOA shall be construed to require FDA/Gulf Coast Seafood Laboratory to use the Corps or to require the Corps to provide any goods or services to FDA/Gulf Coast Seafood Laboratory.

ARTICLE III - INTERAGENCY COMMUNICATIONS

To provide for consistent and effective communication between the Corps and FDA/Gulf Coast Seafood Laboratory, each party shall appoint a Principal Representative to serve as its central point of contact on matters relating to this MOA.

ARTICLE IV - RESPONSIBILITIES OF THE PARTIES

A. Responsibilities of the U.S. Army Corps of Engineers, Mobile District

1. The Corps shall provide FDA/Gulf Coast Seafood Laboratory with goods or services in accordance with the purpose, terms, and conditions of this MOA.

2. The Corps shall identify authorized Corps representatives as points-of-contact.
3. The Corps shall provide the stated goods or services by in-house effort.
4. The Corps shall propose an Estimated Cost Schedule for each fiscal year based on the number of FDA / Gulf Coast Seafood Laboratory employees to be served by the Corps. For subsequent FYs, the Corps shall provide a revised Estimated Cost Schedule.
5. The Corps shall negotiate in good faith, a final agreement as to costs.
6. The Corps shall provide detailed financial reports to the FDA / Gulf Coast Seafood Laboratory. Financial reports shall include information on all funds received, obligated, and expended, and on forecast obligations and expenditures.

B. Responsibilities of the FDA / Gulf Coast Seafood Laboratory

1. The FDA / Gulf Coast Seafood Laboratory shall certify that MOA complies with the requirements of the Economy in Government Act.
2. The FDA / Gulf Coast Seafood Laboratory shall pay all costs associated with the Corps' provisions of goods or services under this MOA and shall certify, at the time of signing, the availability of funds for such goods and services. Actual transfer of funds will take place under an Interagency agreement negotiated between FDA and the Corps specifically for this purpose.
3. The FDA / Gulf Coast Seafood Laboratory shall ensure that only authorized FDA / Gulf Coast Seafood Laboratory official signs this MOA.
4. The FDA / Gulf Coast Seafood Laboratory shall negotiate in good faith, a final agreement as to costs.

ARTICLE V - FUNDING

The FDA / Gulf Coast Seafood Laboratory shall pay all costs associated with the Corps' provision of goods or services under this MOA. The cost to the FDA / Gulf Coast Seafood Laboratory is a flat rate of \$150 per employee. The FDA / Gulf Coast Seafood Laboratory shall determine the total number of employees that will receive services under this MOA, and calculate the total estimated annual costs. (See Appendix A) Each month, the Corps shall bill, and the FDA / Gulf Coast Seafood Laboratory shall pay the expenses incurred.

ARTICLE VI - APPLICABLE LAWS

This MOA and all documents and actions pursuant to it shall be governed by the applicable statutes, regulations, directives, and procedures of the United States. Unless otherwise required by law, all work undertaken by the Corps shall be governed by Corps policies and procedures.

ARTICLE VII - DISPUTE RESOLUTION

The parties agree that, in the event of a dispute between the parties, the FDA / Gulf Coast Seafood Laboratory and the Corps shall use their best efforts to resolve that dispute in an informal fashion through consultation and communication, or other forms of non-binding alternative dispute resolution mutually acceptable to the parties. The parties agree that, in the event such measures fail to resolve the dispute, they shall refer it for resolution to the Office of Management and Budget, or such other entity as may be appropriate.

ARTICLE VIII - RESPONSIBILITY FOR COSTS

If liability of any kind is imposed on the United States relating to the Corps' provision of goods or services under this MOA, the Corps will accept accountability for its actions, but the FDA / Gulf Coast Seafood Laboratory shall remain responsible as the program proponent for providing such funds as are necessary to discharge the liability, and all related costs. This obligation extends to all funds legally available to discharge this liability, including funds that may be made legally available through transfer, reprogramming or other means. Should the FDA / Gulf Coast Seafood Laboratory have insufficient funds legally available, including funds that may be made legally available through transfer, reprogramming or other means, they remain responsible for seeking additional funds from Congress for such purpose, although nothing in this MOA shall be construed to imply that Congress will appropriate funds sufficient to meet the liability.

Notwithstanding the above, this MOA does not confer any liability upon the FDA / Gulf Coast Seafood Laboratory for claims payable by the Corps under the Federal Torts Claims Act. Provided further that nothing in this MOA is intended or will be construed to create any rights or remedies for any third party and no third party is intended to be a beneficiary of this MOA.

ARTICLE IX - PUBLIC INFORMATION

Justification and explanation of the FDA / Gulf Coast Seafood Laboratory's programs before Congress and other agencies, departments, and offices of the Federal Executive Branch shall be the responsibility of the FDA / Gulf Coast Seafood Laboratory. The Corps may provide, upon request, any assistance necessary to support the FDA / Gulf Coast Seafood Laboratory's justification or explanations of the FDA / Gulf Coast Seafood Laboratory's programs conducted under this MOA. In general, the FDA / Gulf Coast Seafood Laboratory is responsible for all public information. The FDA / Gulf Coast Seafood Laboratory or the Corps shall make its best efforts to give the other party advance notice before making any public statement regarding work contemplated, undertaken, or completed pursuant this MOA.

ARTICLE X - MISCELLANEOUS

A. Other Relationships or Obligations

This MOA shall not affect any pre-existing or independent relationships or obligations between the FDA / Gulf Coast Seafood Laboratory and the Corps.

B. Survival

The provisions of this MOA which require performance after the expiration or termination of this MOA shall remain in force notwithstanding the expiration or termination of this MOA.

C. Severability

If any provision of this MOA is determined to be invalid or unenforceable, the remaining provisions shall remain in force and unaffected to the fullest extent permitted by law and regulation.

ARTICLE XI - AMENDMENT, MODIFICATION AND TERMINATION

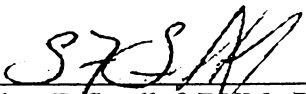
This MOA may be modified or amended only by written, mutual agreement of the parties. Either party may terminate this MOA by providing written notice to the other party. The termination shall be effective upon the sixtieth calendar day following notice, unless a later date is set forth. In the event of termination, the FDA / Gulf Coast Seafood Laboratory shall continue to be responsible for all costs incurred by the Corps under this MOA.

ARTICLE XII - EFFECTIVE DATE

This MOA shall become effective when signed by authorized personnel for both parties.

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

U.S. Army Corps of Engineers,
Mobile District



Stephen F. Sundlof, DVM., Ph.D.
Director, Center for Food Safety
and Applied Nutrition



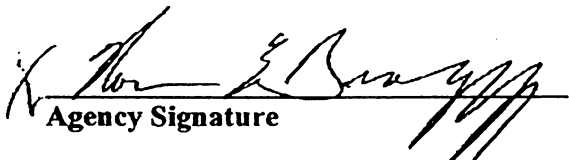
Byron G. Jorns
Colonel, Corps of Engineers
Commanding

Date: 4/28/08

Date: 24 Mar '08

APPENDIX A

<u>Servicing Agency Name and Address</u> U. S. Army Corps of Engineers Occupational Health Services SO-H P.O. box 2288 Mobile, AL 36628-0001	<u>Paying Agency Name and Address</u> U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Gulf Coast Seafood Laboratory 5100 Paint Branch Parkway College Park, MD 20740
<u>Servicing Agency Contact Information</u> Christene Tomlin-Harding, RN Regional Nurse Mgr/Occupational Health Services Christene.v.tomlin-harding@usace.army.mil Tel: (251) 690-2670 Fax: (251) 690-2028 Toll-Free: (866) 521-2774	<u>Paying Agency Contact Information</u> Julia Pryor Administrative Specialist Julia.pryor@fda.hhs.gov Tel: (251) 694-4479 Fax: (251) 694-4477
<u>Reimbursable Interagency Agreement Data</u> <u>Period of Performance</u> Fiscal Year : <u>2008</u> 10/01/2007 through 9/30/2008	<u>Cost of Service Calculation</u> <u>11</u> X <u>\$150 (ea)</u> = <u>\$ 1650.00</u> No. of Employees



Agency Signature

Title

Date

[FR Doc. E8-11521 Filed 5-21-08; 8:45 am]
 BILLING CODE 4160-01-C

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
National Institutes of Health
**Center for Scientific Review; Amended
Notice of Meeting**

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 16, 2008, 8 a.m. to June 17, 2008, 5 p.m., Four Points Sheraton, 1201 K Street, NW., Washington, DC 20005 which was published in the **Federal Register** on May 2, 2008, 73 FR 24296-24298. The meeting will be held June 23, 2008. The meeting time and location remain the same. The meeting is closed to the public.

Dated: May 14, 2008.

Jennifer Spaeth,
*Director, Office of Federal Advisory
 Committee Policy.*

[FR Doc. E8-11304 Filed 5-21-08; 8:45 am]
 BILLING CODE 4140-01-M

**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. 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 Cancer Institute Initial Review Group; Subcommittee H—Clinical Groups.

Date: July 14–15, 2008.

Time: 6:30 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Timothy C. Meeker, MD, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room