DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

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 September 14, 1999, 1 p.m. to 5 p.m., and on September 15, 1999, 8 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 14, 1999, the committee will: (1) Hear reports on recent workshops on Thimerosal in Vaccines and Cell Substrates for Vaccine Development and be updated on recent developments concerning the rotavirus vaccine manufactured by Wyeth Laboratories, Inc., and (2) be briefed on selected individual research programs in the Laboratory of Parasitic Biology and the Laboratory of Biophysics. On September 15, 1999, the committee will discuss the use of immunologic surrogates for demonstration of protective efficacy of meningococcal conjugate vaccines.

Procedure: On September 14, 1999, from 1 p.m. to 3:10 p.m., and on September 15, 1999, from 8 a.m. to 4 p.m., the meeting is open to the public. 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 by September 7, 1999. Oral presentations from the public will be scheduled between approximately 2:10 p.m. and 2:50 p.m. on September 14, 1999, and between approximately 12:10 p.m. and 12:30 p.m. on September 15, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 1999, 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.

Closed Committee Deliberations: On September 14, 1999, from 3:10 p.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications. Also, on September 14, 1999, from 4 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research programs.

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

Dated: August 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–22102 Filed 8-25-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–6002]

Memorandum of Understanding Between the Food and Drug Administration and the State of Iowa

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 State of Iowa. The purpose of the MOU is to establish policies, procedures, and responsibilities for the billing and collection of Mammography Quality Standards Act (MQSA) mammography facility inspection fees for the second year.

DATES: The agreement became effective July 30, 1999.

FOR FURTHER INFORMATION CONTACT: Lireka P. Joseph, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 2094 Gaither Rd., Gaithersburg, MD 20850, 301–443–2845.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this memorandum of understanding.

Dated: August 19, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

BILLING CODE 4160–01–F

July 26, 1999

MEMORANDUM OF UNDERSTANDING

BETWEEN

STATE OF IOWA
DEPARTMENT OF PUBLIC HEALTH
BUREAU OF RADIOLOGICAL HEALTH

AND

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF HEALTH AND INDUSTRY PROGRAMS

RE: AUTHORIZATION OF THE STATE OF IOWA TO PARTICIPATE IN THE U.S. FOOD AND DRUG ADMINISTRATION'S MQSA STATES AS CERTIFIERS DEMONSTRATION PROJECT

Control No. 225-99-6002

MEMORANDUM OF UNDERSTANDING

BETWEEN

STATE OF IOWA
DEPARTMENT OF PUBLIC HEALTH
BUREAU OF RADIOLOGICAL HEALTH

AND

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF HEALTH AND INDUSTRY PROGRAMS

I. PURPOSE:

This Memorandum of Understanding (MOU) establishes policies, procedures, and responsibilities for the billing and collection of Mammography Quality Standards Act (MQSA) mammography facility inspection fees while the State of Iowa is participating in the Food and Drug Administration's (FDA) MQSA States as Certifiers Demonstration Project. The Demonstration Project is now renewable for a second year by mutual agreement.

II. BACKGROUND:

This MOU has been developed because of the need to bill and collect annual mammography facility inspection fees according to provisions contained in the MQSA while the State of Iowa is participating in the demonstration project. The State of Iowa voluntarily applied and agreed to participate in this demonstration project.

Each agency recognizes that this MOU documents a working relationship. It does not infer any contractual obligations nor assumption of liability by one agency for any action of the other agency.

It is understood that each agency continues to exercise its respective jurisdictional authority, and that the cooperation extended to the other agency does not transfer any jurisdictional authorities.

III. SUBSTANCE OF AGREEMENT:

1. The State of Iowa will provide the FDA, within five business days, the results of all annual MQSA inspections and MQSA follow-up inspections conducted by the State

during the demonstration project. Based on this information, the FDA will bill and charge each inspected mammography facility a fee of $509 to cover the FDA's costs for the annual inspection. This fee may be subject to change.

The types of services provided by FDA are as follows:

- Training and certification of inspectors.
- Development of instrument calibration procedures and calibration of instruments used in the inspections.
- Supplying, repairing, and replacing inspection equipment.
- Design, programming, and maintenance of inspection data systems.
- Administrative support attributable to facility inspections.

2. Under the MQSA, all certified mammography facilities except governmental entities are subject to the payment of inspection fees. During the period of time the State of Iowa is participating in the Project, facilities that qualify as government entities will not be required to pay the FDA inspection fee but will be required to recertify their government entity status using the form provided by the FDA.

During the period of time the State of Iowa is participating in the Project, the State Department of Public Health will directly bill and charge all facilities certified by the State to perform mammography under MQSA an annual certification fee of $850 for the first unit and $300 for each additional unit.

IV. DEFINITION:

1. Governmental Entity

A "governmental entity" is a mammography facility subject to the MQSA inspection that meets all of the following criteria:

The entire salary of all on-site personnel of the mammography facility is directly paid by a federal department, state, district, territory, possession, federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof, the building, office, or other space occupied by the mammography facility is owned by, rented by, or leased to a federal department, state, district, territory, possession, federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof, the facility's mammography equipment is owned by, rented by, or leased to a federal department, state, district, territory, possession, federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof, and a federal department, state, district, territory, possession, federally-recognized Indian tribe, city, county, town, village, municipal corporation or

similar political organization or subpart thereof has the ultimate authority to make day-to-day decisions concerning the management and operation of the mammography facility.

or

A facility qualifies as a government entity if at least 50% of the mammography screening examinations provided during the preceding 12 months were funded under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k et seq.

V. AUTHORITY

The FDA is vested with authority under section 354(r) of the Public Health Services Act (the PHS Act) (42 U.S.C. 262 *et seq.*) to assess and collect fees from mammography facilities to cover the costs of annual inspections required by the MQSA. Under 354(q) of the PHS Act, FDA may approve a state to perform some of the agency's certification functions. The MQSA amended Title III of the PHS Act by adding a new section 354 (42 U.S.C. 263b) to require uniform national quality standards for mammography facilities.

The State of Iowa is authorized by State statute, Iowa Code Chapter 136.15

VI. NAME AND ADDRESSES OF PARTICIPATING AGENCIES:

A. FDA:

Office of Health and Industry Programs
1350 Piccard Drive
Rockville, MD 20850

B. State of Iowa:

Department of Public Health
Bureau of Radiological Health
Lucas State Office Building
321 E. 12th Street
Des Moines, IA 50319-0075

VII. LIAISON OFFICERS:

A. For FDA:

Lireka P. Joseph, Dr. P.H.

Director
Office of Health and Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration

B. For State of Iowa:

Donald A. Flater
Chief
Bureau of Radiological Health
Iowa Department of Public Health

VIII. PERIOD OF AGREEMENT:

After acceptance by both parties, this MOU will be become effective on or after July 1, 1999 and continue until the completion of the demonstration project or upon termination in writing by either party with a 30-day prior notice (such notice shall be sent to the addresses listed in Section V). This MOU may be modified by mutual written consent at any time. The effective date will be specified in the letter formally approving the State of Iowa as a participant in the demonstration project.

IX. CONCURRENCE:

FDA:

7/26/99
(Signature and date)
Lireka P. Joseph, Dr.P.H.
Director
Office of Health and Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration

State of Iowa:

7-30-99
(Signature and date)
Donald A. Flater
Chief
Bureau of Radiological Health
Iowa Department of Public Health

7-30-99
(Signature and date)
Dr. Stephen C. Gleason, D.O.
Director
Iowa Department of Public Health

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