Respondents	Number of respondents	Number of responses/respondents	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Pediatricians	900	1	0.33	297

Dated: June 4, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–14832 Filed 6–10–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1719]

Angus Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Angus Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 4-(Diiodomethylsulfonyl) toluene as a slimicide in the manufacture of food-contact paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4668) has been filed by Angus Chemical Co., c/o Phillip A. Johns, 10900 Silent Wood Pl., North Potomac, MD 20878–4829. The petition proposes to amend the food additive regulations in § 176.300 *Slimicides* (21 CFR 176.300) to provide for the safe use of 4-(Diiodomethylsulfonyl) toluene as a slimicide in the manufacture of food-contact paper and paperboard.

The agency has determined under 21 CFR 25.32(q) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 24, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–14839 Filed 6–10–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1174]

Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of May 13, 1999 (64 FR 25889). The document announced a public meeting to solicit comments that will assist the Center for Food Safety and Applied Nutrition to develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act. The document published with an incorrect date for the submission of written comments. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Naomi Kulakow, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8682, FAX 202–260–8957, e-mail ''nkulakow@bangate.fda.gov''.

In FR Doc. 99–12039, appearing on page 25889 in the **Federal Register** of Thursday, May 13, 1999, the following corrections are made:

1. On page 25889, in the third column, under the ''Dates'' caption, ''May 28, 1999.'' is corrected to read ''August 20, 1999.''

2. On page 25890, in the third column, under the ''Comments'' section, in the second line, ''May 28, 1999,'' is corrected to read ''August 20, 1999,''.

Dated: June 7, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–14840 Filed 6–10–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–98–4001]

Memorandum of Understanding Between the Food and Drug Administration and States 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 the FDA and the State of Iowa Department of Public Health. The purpose of the MOU is to establish policies, procedures, and responsibilities for the billing and collection of mammography facility inspection fees under the Mammography Quality Standards Act.

DATES: The agreement became effective July 14, 1998.

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 MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: June 4, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

BILLING CODE 4160–01–F

July 8, 1998

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: BILLING AND COLLECTION OF MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) MAMMOGRAPHY FACILITY INSPECTION FEES IN STATES PARTICIPATING IN THE U.S. FOOD AND DRUG ADMINISTRATION'S MQSA STATES AS CERTIFIERS DEMONSTRATION PROJECT

Control No. 225-98-4001

1b

Number assigned: 225-98-4001

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 for one year, but may be 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.

The MQSA constrains the disposition of inspectional fees collected under section (r). Subparagraph (r)(1)(B)(i) provides that fees collected from facilities to cover the costs of inspections "shall be deposited as an offsetting collection of the appropriations for the Department of Health and Human Services (DHHS) as provided in appropriations Acts and shall remain available without fiscal limitation." This language requires the inspectional entity, whether the FDA, a

1c

State under contract, or a certifying State, to deposit funds collected from facilities for inspections into a DHHS account. All inspection funds collected under this MOU will be deposited into the DHHS account initially, then apportioned between FDA and the State according to the inspection costs of each.

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 mail a bill to the inspected mammography facilities to cover the costs of the annual inspections. The bill will set forth the type of inspection conducted (annual or follow-up), the fee to be paid, and the date payment is due (30 days after billing date). Inspection fees will be billed to and collected from the party that operates the facility. If the facility is owned or controlled by an entity other than the operator, it is up to the owner and the operator to establish, through contract or otherwise, how the costs of facility inspections will be paid.

   If full payment is not received by the due date, a second bill will be sent. At that time, interest will begin to accrue at the prevailing rate set by the Department of the Treasury (currently, the prevailing rate is 14.00 percent), a 6.00 percent late payment penalty will be assessed in accordance with 45 CFR 30.13, and a $20 administrative fee will be assessed for each 30-day period that a balance remains due. If payment is not received within 30 days of a third and final bill, FDA may initiate action to collect unpaid balances (with interest and penalties), including the use of collection agencies and reporting of delinquencies to commercial credit reporting agencies.

2. The fees for annual MQSA mammography facility inspections have been determined by the fees set by the State of Iowa. The total fee billed to the facility for each annual MQSA inspection during the demonstration project will be the State fee of $850 for the first unit and $300 for each additional unit plus $509; thus, the total fee will be $1359 plus $300 for each additional unit. The FDA will retain the $509 from each annual MQSA inspection fee for mammography facility inspection-related services provided to the State of Iowa. The types of services that will be provided by the FDA are as follows:

   - Billing facilities for fees due for annual inspections.
   - Collecting facility payments.
   - 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.

1d

- Administrative support attributable to facility inspections.

3. The FDA will pay the State of Iowa $850 for the first unit and $300 for each additional unit for each annual MQSA inspection fee collected from non-governmental entity mammography facilities for inspections conducted by the State during the demonstration project. The State of Iowa will be paid monthly beginning approximately 60 days after receipt of the first inspection record file from Iowa. This monthly payment amount will be based upon the actual amount collected from mammography facilities from the previous month as opposed to the number of inspections conducted during that period. That is, the State of Iowa will receive $850 for the first unit and $300 for each additional unit for each annual MQSA inspection fee which is collected in full by the FDA during each month the State is participating in the demonstration project. Payment will be made electronically. The data contained in the attached Automated Clearinghouse (ACH) information sheet will be utilized by the FDA to pay the State of Iowa for annual MQSA inspections and MQSA follow-up inspections conducted during the demonstration project.

4. 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 demonstration project, the FDA will not pay the State of Iowa, under this MOU, for annual MQSA inspections of mammography facilities which are government entities. FDA will reimburse the State of Iowa for annual MQSA inspections of facilities which are governmental entities through a modification of the MQSA inspection contract between the FDA and the State of Iowa entered into on February 1, 1998. The contract will be extended to cover one year from the effective date of the demonstration project. Should the State cease participating in, or be terminated from, the demonstration project, an MQSA inspection contract may be re-negotiated.

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,

1e

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

1f

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, 1998 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:

(Signature and date) 7/9/98
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:

Donald A. Flater 7/14/98
(Signature and date)
Donald A. Flater
Chief
Bureau of Radiological Health
Iowa Department of Public Health

(Signature and date) 7/14/98
Christopher G. Atchison
Director
Iowa Department of Public Health

[FR Doc. 99–14796 Filed 6–10–99; 8:45 am]
BILLING CODE 4160–01–C