

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 890.5275 is amended by revising paragraph (c) to read as follows:

§ 890.5275 Microwave diathermy.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999, for any microwave diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a microwave diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other microwave diathermy described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

3. Section 890.5300 is amended by revising paragraph (c) to read as follows:

§ 890.5300 Ultrasonic diathermy.

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(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999, for any ultrasonic diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasonic diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasonic diathermy described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

4. Section 890.5860 is amended by revising paragraph (c) to read as follows:

§ 890.5860 Ultrasound and muscle stimulator.

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(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasound and muscle stimulator described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: April 7, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-9220 Filed 4-13-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 98N-0728]

Quality Mammography Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing mammography. The purpose of these amendments is to eliminate a conflict between the mammography regulations, which must be followed by all facilities performing mammography, and FDA's electronic product radiation control (EPRC) performance standards, which establish radiation safety performance requirements for x-ray units, including mammographic systems.

DATES: This regulation is effective on April 28, 1999.

FOR FURTHER INFORMATION CONTACT: Roger L. Burkhart, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

SUPPLEMENTARY INFORMATION:

I. Background

The Mammography Quality Standards Act (MQSA) (Pub. L. 102-539) was signed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, had to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA.

A specific requirement of MQSA was that quality standards be established for mammographic equipment and practices, including quality assurance and quality control programs. Mammography facilities had to meet these standards to become accredited and certified. The standards were intended to replace the patchwork of Federal, State, and private standards existing in 1992 to ensure that all women nationwide receive uniformly high quality mammography services. Since October 1, 1994, these standards have been provided by interim rules published in the **Federal Register** of December 21, 1993 (58 FR 67558 and 58 FR 67565), and amended in the **Federal Register** of September 30, 1994 (59 FR 49808).

In the **Federal Register** of April 3, 1996 (61 FR 14856, 61 FR 14870, 61 FR 14884, 61 FR 14898, and 61 FR 14908), FDA proposed regulations to replace the interim regulations. Developed with strong congressional encouragement, these proposed regulations reflected FDA's belief that more comprehensive quality standards would further optimize facility performance. After analysis of the extensive public comments received on the proposed regulations, revisions were made and a final rule was published in the **Federal Register** of October 28, 1997 (62 FR 55852). The effective date for most of the final rule is April 28, 1999. A few equipment and equipment quality assurance requirements do not become effective until October 28, 2002.

FDA has subsequently discovered that some mammographic x-ray systems will have difficulty meeting certain of the new requirements because of design features that were used by the manufacturers in order to ensure that their units met the agency's EPRC performance standards for diagnostic x-ray systems. To resolve this conflict, proposed amendments to the MQSA regulations were published in the

Federal Register of November 5, 1998 (63 FR 59750).

II. Need for Amendments

The source of the conflict lies in the requirements for the collimation of the x-ray field and the alignment of that field with the image receptor found in § 900.12(b)(5) and (e)(5)(vii) (21 CFR 900.12(b)(5) and (e)(5)(vii)) of the MQSA final regulations. Two problems exist with these provisions as they appeared in the October 28, 1997, publication.

First, both of these provisions permit the x-ray field "to extend to or beyond the edges of the image receptor." This allowance was made in response to the expressed desire of some mammography facilities to have the capacity to "blacken" the film to the edges, a capacity that is particularly useful when automated viewing devices are used. However, the manufacturers of all diagnostic x-ray systems, including mammography systems, must comply with applicable performance standards established by FDA. These performance standards currently require that mammography systems be manufactured with collimation to ensure that the x-ray field does not extend beyond the nonchest wall edges of the image receptor.

It is possible for a mammography system to meet both of these sets of standards as they were originally written. However, FDA has been informed by several manufacturers that in the past, in order to be sure to meet the EPRC standards, their systems were designed so that the x-ray field does not reach the nonchest wall edges of the image receptor. Such systems would not meet the final MQSA regulations as presently written.

Without an amendment to the MQSA regulations, in order to be in compliance, some facilities would have to choose among three courses of action. The first would be to apply for and receive approval of an alternative requirement for alignment under 21 CFR 900.18 of the MQSA regulations that would allow the facility to continue using its system unchanged. The second would be to purchase a retrofit of their system under a variance to the performance standards that has already been approved by FDA for one manufacturer. The third would be to purchase a new system that meets both sets of existing requirements.

FDA proposed solving this first problem by amending § 900.12(e)(5)(vii) so that the x-ray field will be allowed, but not required as at present, to extend to or beyond the nonchest wall sides of the image receptor. This would permit facilities whose systems are not

presently capable of "blackening" the films to these edges to continue to use those systems without the need of either applying for an alternative requirement or purchasing an expensive retrofit or new unit.

The second problem is that the limit on the extension of the x-ray field beyond all edges of the image receptor to "within 2 percent of the SID", discussed on page 62 FR 55852 at 55945 of the preamble of the October 27, 1997, final rule, was erroneously applied in the regulations only to the chest wall side of the image receptor. This omission raises the possibility of an unnecessary radiation hazard to the patient if the x-ray field extends an excessive amount beyond the nonchest wall edges of the image receptor. The agency proposed to remove this radiation hazard concern by amending § 900.12(e)(5)(vii) to apply the 2 percent of the SID extension limit to all edges of the image receptor, in accordance with the intentions expressed in the preamble.

Finally, FDA proposed to simplify the regulations by dropping all mention of alignment from § 900.12(b)(5), thus consolidating all alignment requirements at one location in § 900.12(e)(5)(vii). The portion of § 900.12(b)(5) dealing with the light field remains unchanged.

III. Comments on the Proposed Amendments

FDA invited interested persons to comment on the November 5, 1998, proposed rule by January 4, 1999. FDA received two comments. One comment from a professional organization supported the amendments, noting that they would "eliminate conflict" between the two sets of regulations, "address user concerns," and take into account "cost concerns" of facilities. The second comment, from a State radiation control agency, simply expressed support for the amendments. In view of these responses, the agency has decided to make the amendments final.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(c) that the action of publication of the MQSA final regulations is of a 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.

V. Analysis of Impacts

FDA has examined the impacts of this rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that this final rule will not have a significant negative economic impact on a substantial number of small entities. This rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

FDA had previously estimated (62 FR 55852 at 55968) that the expected average annual benefits from the final regulations would range between \$181.7 million and \$262.7 million. Average annual compliance costs were estimated at \$38.2 million. The compliance cost estimate did not include the possible added costs related to the alignment requirement discussed previously, as the difficulty noted by the manufacturers was not foreseen during the development of the regulations. These added costs would be minimal if an alternative requirement was applied for and received but would be more significant if retrofitting or purchase of a new unit was carried out to meet the requirement. However, FDA's amending of the regulations will eliminate the requirement leading to the possible extra costs and thus eliminate any possible extra cost.

VI. Paperwork Reduction Act of 1995

The agency has determined that this final rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

2. Section 900.12 is amended by revising paragraphs (b)(5) and (e)(5)(vii)(A) to read as follows:

§ 900.12 Quality standards.

* * * * *

(b) * * *

(5) *Light fields.* For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

* * * * *

(e) * * *

(5) * * *

(vii) * * *

(A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

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Dated: April 7, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-9222 Filed 4-13-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300830; FRL-6071-3]

RIN 2070-AB78

Pyriproxyfen (2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyriproxyfen in or on pome fruits, walnuts and apple pomace, wet. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 14, 1999. Objections and requests for hearings must be received by EPA on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300830], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300830], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by

the docket control number [OPP-300830]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 222, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6411, tavano.joseph@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 27, 1998 (63 FR 14926) (FRL-5579-6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) announcing the filing of a pesticide petition (PP 7F4882) for tolerance by Valent U.S.A. Corporation, 1333 N. California Blvd., Walnut Creek, CA 94596. This notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.510 be amended by establishing a tolerance for residues of the insecticide, pyriproxyfen, in or on pome fruits, walnuts and apple pomace, wet at 0.2, 0.02 and 0.8 part per million (ppm) respectively.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."