substantial number of the data elements will not be known, but as much information as possible should be provided. The minimum information for the transmission of a safety report should include an identifiable patient, an identifiable reporter, a reaction/event, and a suspect drug or biological product.

Dated: October 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29564 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing mammography that published in a document entitled ''Quality Mammography Standards.'' 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: Submit written comments on the proposed rule by January 4, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 (the 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, 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 the 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).

On April 3, 1996, FDA proposed final regulations to replace the interim regulations (61 FR 14856, 14870, 14884, 14898, and 14908). Developed with strong congressional encouragement, these proposed final 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 on 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. The purpose of these amendments is to resolve this conflict.

II. Need for Proposed 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)(A) (21 CFR 900.12(b)(5) and (e)(5)(vii)(A)) of the MQSA final regulations. Two problems exist with these provisions as they appeared in the **Federal Register** of October 28, 1997.

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. Masking clear borders of mammography films is difficult to accomplish with such devices. 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 are currently written. However, FDA has been informed by one manufacturer 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. Units of other manufacturers may have the same problem.

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 is proposing to solve this first problem by changing § 900.12(e)(5)(vii)(A) 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.

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 at 62 FR 55852 at 55945 of the regulation preamble 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 is proposing to remove the radiation hazard concern by amending § 900.12(e)(5)(vii)(A) to apply the 2 percent of the source-image receptor distance (SID) extension limit to all edges of the image receptor, in accordance with the intentions expressed in the preamble.

Finally, FDA is also proposing 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)(A). The portion of § 900.12(b)(5) dealing with the light field remains unchanged.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this action 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.

IV. Analysis of Impacts

FDA has examined the impact 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 rule, if finalized, will not have a significant 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 1 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 to $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 one manufacturer 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 purchasing of a new unit was carried out to meet the requirement. However, amending the regulations as proposed by FDA would eliminate the requirement leading to the possible extra costs and thus eliminate any possible extra cost.

V. Paperwork Reduction Act of 1995

The agency has tentatively determined that this proposed 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 removing paragraph (b)(5)(i) and by redesignating paragraph (b)(5)(ii) as paragraph (b)(5), by revising newly redesignated paragraph (b)(5), and by revising paragraph (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 two percent of the SID.

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Dated: September 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29563 Filed 11–4–98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–180P]

21 CFR Parts 1308 and 1312

Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol (Martinol®; (-)-Δ^9-(trans)-Tetrahydrocannabinol in Sesame oil and Encapsulated in Soft Gelatin Capsules) From Schedule II to Schedule III.

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) to remove the Food and Drug Administration (FDA) approved drug product containing dronabinol [Marinol®; (-)-Δ^9-(*trans*)-tetrahydrocannabinol in sesame oil and encapsulated in soft gelatin capsules] from Schedule II and place it into Schedule III of the Controlled Substances Act (CSA). This proposed action is based on an evaluation of the relevant data by the DEA and a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS)