Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0583]

RIN 0910–AB16

Exports: Notification and Recordkeeping Requirements; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 16, 1999, the comment period for the proposed rule that appeared in the **Federal Register** of April 2, 1999 (64 FR 15944). The proposed rule would establish the notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. FDA is taking this action in response to numerous issues raised by the proposed rule thus far.

DATES: Written comments by July 16, 1999.

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

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Pub. L. 104–134, as amended by Pub. L. 104–180) significantly changed the export requirements for unapproved human drugs, biologics, devices, and animal drugs. For example, before the law was enacted, most exports of unapproved new drug products could only be made to the 21 countries then identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to numerous restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new human drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA) and certain other requirements are met (see section 802(b)(1)(A) of the act). Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA. This provision of section 802 of the act also applies to the export of certain devices that cannot be sold or marketed in the United States.

The FDA Export Reform and Enhancement Act also modified the export authority in section 801 of the act (21 U.S.C. 381). Before enactment of the FDA Export Reform and Enhancement Act, section 801(e)(1) of the act applied to the exportation of certain foods, drugs, devices, and cosmetics. Products exported under section 801(e) of the act are not considered adulterated or misbranded if the product intended for export: (1) Meets the foreign purchaser's specifications; (2) is not in conflict with the laws of the country to which it is being exported; (3) is labeled on the outside of the shipping package that the product is intended for export; and (4) is not sold or offered for sale in domestic commerce (see section 801(e)(1) of the act). Additional requirements apply to certain devices (see section 801(e)(2) of the act). The FDA Export Reform and Enhancement Act extended these four basic requirements to all exports under sections 801 and 802 of the act, and to exports of partially processed biologics under section 351(h) of the Public Health Service Act (the PHS Act) (42 U.S.C. 262(h)) (see section 801(e) and (f) of the act); section 802(f)(3) of the act; and section 351(h) of the PHS Act, and made section 801(e) of the act the principal export authority for the exportation of unapproved animal drugs other than animal drugs banned in the United States. It also imposed additional labeling requirements on certain exports of approved drugs (see section 801(f) of the act).

The FDA Export Reform and Enhancement Act also established recordkeeping and notification requirements. Products exported under section 802 of the act are subject to certain requirements under section 802(f) and (g) of the act. Section 802(f) of the act prohibits a drug or device from being exported under section 802 of the act if it: (1) Does not conform with current good manufacturing practices; (2) is adulterated under certain provisions in section 501 of the act (21 U.S.C. 351); (3) does not comply with section 801(e)(1) of the act; (4) is the subject of a determination by FDA or the U.S. Department of Agriculture (with respect to veterinary biologics) that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States; (5) would present an imminent hazard to the public health of the foreign country; (6) fails to comply with labeling requirements in the country receiving the exported drug or device; or (7) is not promoted in accordance with labeling requirements.

Section 802(g) of the act requires an exporter of a drug or device under section 802(b)(1)(A) of the act to provide a ''simple notification'' to the agency ''identifying the drug or device when the exporter first begins to export such drug or device'' to any of the 25 countries identified in section 802(b)(1)(A) of the act. For exports to other, nonlisted countries, section 802(g) of the act requires the exporter to provide a simple notification ''identifying the drug or device and the country to which such drug or device is being exported.'' This section also requires persons export under any provision of section 802 of the act to ''maintain records of all drugs or

devices exported and the countries to which they were exported.''

In the **Federal Register** of April 2, 1999 (64 FR 15944), FDA published a proposed rule that would establish the notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. Because reactions to the proposed rule thus far have raised numerous issues, the agency wants to ensure that interested persons have an adequate opportunity to examine the rule and to submit comments. Therefore, FDA is extending the comment period until July 16, 1999.

Interested persons may, on or before July 16, 1999, submit to the Dockets Management Branch (address above) written comments on the proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the proposed rule and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The proposed rule may also be obtained through FDA's web site at ''www.FDA.gov''.

Dated: June 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–15395 Filed 6–15–99; 10:04 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 99N–1502]

Quality Mammography Standards; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing mammography. The purpose of the amendments is to incorporate changes required by the Mammography Quality Standards Reauthorization Act (MQSRA). This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Comments on this proposal must be received by August 31, 1999. If FDA receives no significant adverse comment on the provisions of these regulations within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective November 1, 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 20857, 301–594–3332.

SUPPLEMENTARY INFORMATION: This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule is identical to the direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and the direct final rule is withdrawn. FDA is publishing the direct final rule because the rule contains direct incorporations of statutory mandates, and FDA anticipates that it will receive no significant adverse comments. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect no later than 135 days after publication. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives significant adverse comments regarding this rule, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to the comments under this rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. It should be remembered, however, that the requirements themselves were established by the MQSRA. FDA must implement these new statutory provisions.

In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a note-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered a significant adverse comment under this procedure. For example, a comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the comment shows how the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

I. Background

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

Facilities were initially accredited and certified if they met the standards contained within the interim rules issued by FDA in the **Federal Register** of December 21, 1993 (58 FR 67558 and 58 FR 67565), and amended by another interim rule published in the **Federal Register** of September 30, 1994 (59 FR 49808). More comprehensive standards were proposed by FDA in the **Federal Register** of April 3, 1996 (61 FR 14856,