FEDERAL TRADE COMMISSION

16 CFR Part 305

Rule Concerning Disclosures Regarding Energy Consumption and Water Use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act (''Appliance Labeling Rule'')

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission amends its Appliance Labeling Rule by publishing new ranges of comparability to be used on required labels for clothes washers.

EFFECTIVE DATE: September 15, 1999.

FOR FURTHER INFORMATION CONTACT: James Mills, Attorney, Division of Enforcement, Federal Trade Commission, Washington, DC 20580 (202–326–3035).

SUPPLEMENTARY INFORMATION:

The Appliance Labeling Rule (''Rule'') was issued by the Commission in 1979, 44 FR 66466 (Nov. 19, 1979), in response to a directive in the Energy Policy and Conservation Act of 1975.[1] The Rule covers eight categories of major household appliances. Clothes washers are among those categories. The Rule also covers pool heaters, 59 FR 49556 (Sept. 28, 1994), and contains requirements that pertain to fluorescent lamp ballasts, 54 FR 28031 (July 5, 1989), certain plumbing products, 58 FR 54955 (Oct. 25, 1993), and certain lighting products, 59 FR 25176 (May 13, 1994, eff. May 15, 1995).

The Rule requires manufacturers of all covered appliances and pool heaters to disclose specific energy consumption or efficiency information (derived from the DOE test procedures) at the point of sale in the form of an ''EnergyGuide'' label and in catalogs. It also requires manufacturers of furnaces, central air conditioners, and heat pumps either to provide fact sheets showing additional cost information, or to be listed in an industry directory showing the cost information for their products. The Rule requires manufacturers to include, on labels and fact sheets, an energy consumption or efficiency figure and a ''range of comparability.'' This range shows the highest and lowest energy consumption or efficiencies for all comparable appliance models so consumers can compare the energy consumption or efficiency of other models (perhaps competing brands) similar to the labeled model. The Rule also requires manufacturers to include, on labels for some products, a secondary energy usage disclosure in the form of an estimated annual operating cost based on a specificed DOE national average cost for the fuel the appliance uses.

Section 305.8(b) of the Rules requires manufacturers, after filing an initial report, to report certain information annually to the Commission by specified dates for each product type.[2] These reports, which are to assist the Commission in preparing the ranges of comparability, contain the estimated annual energy consumption or energy efficiency ratings for the appliances derived from tests performed pursuant to the DOE test procedures. Because manufacturers regularly add new models to their lines, improve existing models, and drop others, the data base from which the ranges of comparability are calculated is constantly changing. To keep the required information consistent with these changes, under § 305.10 of the Rule the Commission will publish new ranges (but not more often than annually) if an analysis of the new information indicates that the upper or lower limits of the ranges have changed by more than 15%. Otherwise, the Commission will publish a statement that the prior ranges remain in effect for the next year.

Manufacturers of clothes washers have made the required annual submissions of data for this product category. In analyzing the data, the Commission has found that there has been a significant change of more than 15% in the ranges. Accordingly, the Commission is publishing new ranges of comparability for the clothes washer category. These ranges will supersede the current ranges for clothes washers, which were published originally on April 20, 1998 (63 FR 19398), and which became effective August 12, 1998.

In consideration of the foregoing, the Commission revises Appendix F of its Appliance Labeling Rule by publishing the following ranges of comparability for use in required disclosures (including labeling) for clothes washers manufactured on or after September 15, 1999. In addition, as of this effective date, manufacturers must base the disclosures of estimated annual operating cost required at the bottom of the EnergyGuide for clothes washers on the 1999 Representative Average Unit Costs of Energy for electricity (8.22 cents per kiloWatt-hour) and natural gas (68.8 cents per therm) that were published by DOE on January 5, 1999, 64 FR 487, and by the Commission on February 17, 1999, 64 FR 7785.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to a Regulatory Flexibility Act analysis (5 U.S.C. 603–604) are not applicable to this proceeding because the amendments do not impose any new obligations on entities regulated by the Appliance Labeling Rule. Thus, the amendments will not have a ''significant economic impact on a substantial number of small entities'' (5 U.S.C. 605). The Commission has concluded, therefore, that a regulatory flexibility analysis is not necessary, and certifies, under section 605 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that the amendments announced today will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act (''PRA''), 44 U.S.C. 3501 *et seq.*, requires government agencies, before promulgating rules or other regulations that require ''collections of information'' (*i.e.*, recordkeeping, reporting, or third-party disclosure requirements), to obtain approval from the Office of Management and Budget (''OMB''), 44 U.S.C. 3502. The Commission currently has OMB clearance for the Rule's information collection requirements (OMB No. 3084–0069). The amendment will not impose any new information collection requirements. Instead, it will provide manufacturers with revised ranges of comparability to use on the EnergyGuide labels already required by the Rule.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

2. Appendix F to Part 305 is revised to read as follows:

Appendix F to Part 305—Clothes Washers

Range Information: ''Compact'' includes all household clothes washers

[1] 42 U.S.C. 6294. The statute also requires the Department of Energy (''DOE'') to develop test procedures that measure how much energy the appliances use, and to determine the representative average cost a consumer pays for the different types of energy available.

[2] Reports for clothes washers are due March 1.

with a tub capacity of less than 1.6 cu. ft. or 13 gallons of water.

''Standard'' includes all household clothes washers with a tub capacity of 1.6 cu. ft. or 13 gallons of water or more.

Capacity	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
COMPACT	.....	.....
Top Loading	537	607
Front Loading	(*)	(*)
STANDARD	.....	.....
Top Loading	294	1154
Front Loading	156	314

(*) No Data Submitted

By direction of the Commission.

Donald S. Clark,

Secretary.

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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

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing mammography. The amendments are intended to incorporate changes required by the Mammography Quality Standards Reauthorization Act (MQSRA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event that the agency withdraws the direct final rule.

DATES: This regulation is effective November 1, 1999. Submit written comments on or before August 31, 1999. If FDA receives no significant adverse comments 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 this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

ADDRESSES: Submit written comments on the direct final 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:

I. Background

The Mammography Quality Standards Act (Pub. L. 102–539) (the MQSA) 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 67565), and amended by another interim rule published in the **Federal Register** on September 30, 1994 (59 FR 49808). More comprehensive standards were proposed by FDA in the **Federal Register** of April 3, 1996 (61 FR 14856, 61 FR 14870, 61 FR 14884, 61 FR 14898, and 61 FR 14908). After some revision in response to the approximately 8,000 comments received on the proposed rule, a final rule amending part 900 (21 CFR part 900) was published in the **Federal Register** of October 28, 1997 (62 FR 55852) (hereinafter referred to as the October 1997 final rule). The effective date of most of the new standards contained within the final rule is April 28, 1999, but a few will not become effective until October 28, 2002.

On October 9, 1998, the MQSRA (Pub. L. 105–248) became law. The basic purpose of the MQSRA was to extend the authorities established by the MQSA until September 30, 2002. However, the MQSRA also contained a requirement that was significantly different from the corresponding requirement in the October 1997 final rule (62 FR 55852). Although this MQSRA requirement will become effective on April 28, 1999, with or without the amendment of the final rule, FDA decided to amend the final rule to incorporate the change. The purpose of this amendment is to provide to the mammography facilities the convenience of being able to find all of the quality standards within a single document instead of having to consult both the October 1997 final rule and the MQSRA and to avoid confusion as to the applicable reporting requirement.

Other provisions of the MQSRA clarify the basis for some of the requirements contained within the October 1997 final rule. FDA is also amending the final rule to conform its wording of those requirements to that of the statute.

II. Changes in the Regulations

A. Reporting Requirements

Section 900.12(c)(2) (21 CFR 900.12(c)(2)) of the Ocotober 1997 final rule describes the requirements for communicating mammography results to the patients. As published in the October 1997 final rule, these requirements mandated that each mammography facility have a system to ensure that the results of each examination are communicated to the patient in a timely manner. Patients without a referring health care provider were to be sent the report of the examination (as described in § 900.12(c)(1)) directly by the mammography facility, along with a written notification or summary of the results in lay terms. It was further required by the October 1997 final rule that such self-referred patients should be referred to a health care provider when clinically indicated.

In the case of patients with a referring health care provider, § 900.12(c)(3) required that the health care provider receive the report of the examination. The facility's system for ensuring that results reached the patient could utilize the services of that health care provider to achieve that goal. There was no specific requirement that a summary in lay terms be provided to the patient with a referring health care provider.

The MQSRA amended the MQSA to specifically require that all patients, not just self-referred patients, receive directly from the mammography facility, a summary of the written report in terms easily understood by a lay person. As previously noted, this MQSRA requirement will go into effect on April 28, 1999. FDA is amending § 900.12(c)(2) to incorporate this new requirement.