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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: July 20, 1995.

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

SUPPLEMENTARY INFORMATION: Section 324 of the Energy Policy and Conservation Act of 1975 (''EPCA'')[1] requires the Federal Trade Commission to consider labeling rules for the disclosure of estimated annual energy cost or alternative energy consumption information for at least thirteen categories of appliances. Clothes washers are included in those categories. The statute also requires the Department of Energy (''DOE'') to develop test procedures that measure how much energy the appliances use. In addition, DOE is required to determine the representative average cost a consumer pays for the different types of energy available.

On November 19, 1979, the Commission issued a final rule covering seven of the thirteen appliance categories that were then covered by DOE test procedures: refrigerators and refrigerator-freezers, freezers, dishwashers, water heaters, clothes washers, room air conditioners and furnaces (this category includes boilers).[2] The Commission has extended the coverage of the Appliance Labeling Rule (''Rule'') four times since it originally issued the Rule: in 1987 (central air conditioners, heat pumps, and pulse combustion and condensing furnaces);[3] 1989 (fluorescent lamp ballasts);[4] and, 1993 (certain plumbing products[5] and certain lighting products[6]). On July 1, 1994, the Commission amended the Rule to make certain improvements, including making the label format more ''user-friendly,'' changing the energy usage descriptors required on labels, and adopting new product sub-categories for ranges of comparability purposes.[7] In addition to the new format, which applies to labels for all products, the changes for clothes washer labels are the requirement to disclose kilowatt-hour use per year (instead of estimated annual operating cost) for the primary energy usage disclosure and ranges of comparability, and the addition of the ''front-loading'' and ''top-loading'' sub-categories to the ''standard'' and ''compact'' categories.

Section 305.8(b) of the Rule requires manufacturers, after filing an initial report, to report annually by specified dates for each product type.[8] 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 in line with these changes, the Commission is empowered, under § 305.10 of the Rule, to 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 must publish a statement that the prior ranges remain in effect for the next year.

The annual submissions of data for clothes washers have been made and have been analyzed by the Commission. These submissions of data were made by the affected manufacturers in compliance with the new requirements for new energy usage descriptors and sub-categories in the amendments published on July 1, 1994. These ranges will supersede the current ranges for clothes washers, which were published on April 16, 1991.[9]

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 July 20, 1995.

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 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.

[1] 42 U.S.C. 6294.

[2] 44 FR 66466, 16 CFR Part 305 (Nov. 19, 1979). The Statement of Basis and Purpose for the final Rule describes the reasons the Commission declined to cover the other categories of covered products. *Id.* at 66467–69.

[3] 52 FR 46888 (Dec. 10, 1987).

[4] 54 FR 28031 (July 5, 1989).

[5] 58 FR 54955 (Oct. 25, 1993).

[6] 59 FR 25176 (May 13, 1993).

[7] 59 FR 34014. The effective date of the amendments was December 28, 1994. On December 8, 1994, however, the Commission published a partial delay of compliance dates for certain covered products, including clothes washers. 59 FR 63688. As a result of this second notice, manufacturers of clothes washers were given extra time to prepare the new labels. They must begin using the new labels, however, on all covered products manufactured on or after the effective date of today's notice.

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

[9] 56 FR 15274.

Capacity	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Compact:		
Top Loading	607	1,226
Front Loading	(1)	(1)
Standard:		
Top Loading	603	1,818
Front Loading	306	395

1 No data submitted.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 95–9930 Filed 4–20–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 206

[Docket Nos. 88P–0380 and 89P–0163]

Imprinting of Solid Oral Dosage Form Drug Products for Human Use; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; clarification.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations requiring the imprinting of solid oral dosage form drug products for human use. This final rule clarifies FDA's intent regarding the effective date for drug products introduced or delivered for introduction into interstate commerce.

DATES: Effective September 13, 1995; written comments by July 20, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Deborah A. Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 1993 (58 FR 47948), FDA published a final rule requiring the imprinting of all solid oral dosage form drug products for human use. The regulation requires that all drugs covered by it bear an imprint that will permit the identification of the drug product, including its active ingredients and dosage strength, and its manufacturer or distributor. The regulation was based on a proposed rule that was published in the **Federal Register** of May 15, 1991 (56 FR 22370). The preamble to the proposed rule stated that, among other things, any final rule based on the proposal would become effective 1 year after its date of publication in the **Federal Register**. The preamble also stated that any drug product subject to the requirements of this rule that is ''*introduced or delivered for introduction into interstate commerce*''after the effective date would be deemed to be adulterated, misbranded, or an unapproved new drug, unless it is imprinted in compliance with the regulation (see 56 FR 22370 at 22375 (emphasis added)). Under the proposed rule, FDA intended the rule to be effective for drug products entering interstate commerce at the manufacturing level 1 year after the date of publication of a final rule in the **Federal Register**.

In response to the proposed rule, many drug companies commented that 1 year was insufficient time to comply with the requirements of the rule. Industry comments indicated that it would take longer than 1 year for equipment retooling and product imprinting.

In response to industry's concerns, FDA provided for an implementation period of 2 years. The agency intended to provide an effective date of September 13, 1995, which is 2 years after its date of publication in the **Federal Register**.

However, in revising the final rule to provide for a 2-year implementation period, the agency inadvertently replaced the reference to drug products ''introduced or delivered for introduction into interstate commerce'' with a reference to drug products ''*distributed in* interstate commerce'' (see 58 FR 47948 at 47950) (emphasis added). This change created the misimpression that FDA intended the rule to apply to drug products distributed by manufacturers, repackers, and retail distributors, thereby increasing, rather than decreasing, the burden on the pharmaceutical industry. FDA has received inquires expressing concern that FDA intended to initiate recall actions at the retail level because ''distribution'' would include sale at that level.

This final rule amends 21 CFR 206.10(a) by replacing the language ''distributed in interstate commerce'' with ''introduced or delivered for introduction into interstate commerce.'' This will clarify the requirements of the rule as it pertains to products in interstate commerce.

Because this amendment to the imprinting regulations makes only a change necessary to conform the rule to FDA's original intention as stated in the preamble to the proposed rule and to be consistent with the agency's intent to provide a 2-year implementation period as provided for in the final rule, notice and public procedure are unnecessary. FDA finds that there is good cause to dispense with notice of proposed rulemaking, pursuant to 5 U.S.C. 553(b)(3)(B). FDA is therefore publishing this revision as a final rule effective September 13, 1995. However, the agency is giving interested persons 90 days to comment on this final rule.

II. Request for Comments

Interested persons may, on or before July 20, 1995, submit to the Dockets Management Branch (address above) written comments regarding this final 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 206

Drugs.

PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

1. The authority citation for 21 CFR part 206 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 206.10 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 206.10 Code imprint required.

(a) Unless exempted under § 206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. * * *

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