

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 ("Commission") announces that the current ranges of comparability for central air conditioners, and heat pumps will remain in effect until further notice. Finally, the Commission amends the portions of Appendices H (Cooling Performance and Cost for Central Air Conditioners) and I (Heating Performance and Cost for Central Air Conditioners) to reflect the current (2002) Representative Average Unit Cost of Electricity that was published on April 24, 2002 (67 FR 20104), by the Department of Energy ("DOE"), and on June 7, 2002 (67 FR 39269) by the Commission.

EFFECTIVE DATES: The amendments to Appendices H and I to Part 305 will become effective December 16, 2002.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, Division of Enforcement, Federal Trade Commission, Washington, DC 20580 (202-326-2889); hnewsome@ftc.gov.

SUPPLEMENTARY INFORMATION: The 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 ("EPCA").¹ The Rule covers several categories of major household appliances including central air conditioners and heat pumps.

I. Background

The Rule requires manufacturers of all covered appliances 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, fact sheets (for some appliances), and in catalogs. 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

¹ 42 USC 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.

highest and lowest energy consumption or efficiencies for all comparable appliance models so consumers can compare the energy consumption or efficiency of the other models (perhaps competing brands) similar to the label 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 specified DOE national average cost for the fuel the appliance uses.

Section 305.8(b) of the Rule 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 on labels consistent with these changes, the Commission will publish new ranges 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 range remain in effect for the next year.

II. 2002 Central Air Conditioner and Heat Pump Information

The annual submissions of data for central air conditioners, and heat pumps have been made and analyzed by the Commission. The ranges of comparability for central air conditioners and heat pumps have not changed by more than 15% from the current ranges for these products. Therefore, the current ranges for these products, which were published on September 16, 1996 (61 FR 48620), will remain in effect until further notice.

III. Cost Figures for Central Air Conditioner and Heat Pump Fact Sheets

The Commission is amending the cost calculation formulas in Appendices H and I to Part 305 that manufacturers of central air conditioners and heat pumps must include on fact sheets and in directories to reflect this year's energy costs figures published by DOE. These routine amendments will become effective December 16, 2002.

² Reports for central air conditioners and heat pumps are due July 1.

IV. Administrative Procedure Act

The amendments published in this notice involve routine, technical and minor, or conforming changes to the Rule's disclosure requirements so that the information on fact sheets and directories is accurate and up to date. Accordingly, the Commission finds for good cause that public comment for these technical, procedural amendments is impractical and unnecessary (5 USC 553(b)(A)(B) and (d)).

V. 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. These technical amendments merely provide a routine change to the range information required by the 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.

VI. Paperwork Reduction Act

In a June 13, 1988 notice (53 FR 22106), the Commission stated that the Rule contains disclosure and reporting requirements that constitute "information collection requirements" as defined by 5 CFR 1320.7(c), the regulation that implements the Paperwork Reduction Act.³ The Commission noted that the Rule had been reviewed and approved in 1984 by the Office of Management and Budget ("OMB") and assigned OMB Control No. 3084-0068. OMB has reviewed the Rule and extended its approval for its recordkeeping and reporting requirements until September 30, 2004. The amendments now being adopted do not change the substance or frequency of the recordkeeping, disclosure, or reporting requirements and therefore, do not require further OMB clearance.

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:

³ 44 U.S.C. 3501-3520.

PART 305—[AMENDED]

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

Authority: 42 U.S.C. 6294.

2. In section 2 of Appendix H of Part 305, the text is amended by removing the figure “8.29¢” wherever it appears

and by adding, in its place, the figure “8.28¢”. In addition, the text in this section is amended by removing the figure “12.45¢” wherever it appears and by adding, in its place, the figure “12.42¢”.

3. The formula in section 2 of Appendix H of Part 305 is revised to

read as follows in both places that it appears:

Appendix H to Part 305—Cooling Performance and Cost for Central Air Conditioners

* * * * *

$$\text{Your estimated cost} = \frac{\text{Listed average annual operating cost}^* \times \frac{\text{Your cooling load hours}^{**}}{1,000} \times \frac{\text{Your electrical rate in cents per KWH}}{8.28\text{¢}}}{1,000}$$

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4. In section 2 of Appendix I of Part 305, the text is amended by removing the figure “8.29¢” wherever it appears and by adding, in its place, the figure “8.28¢”. In addition, the text and formulas are amended by removing the

figure “12.45¢” wherever it appears and by adding, in its place, the figure “12.42¢”.

5. In section 2 of Appendix I of Part 305, the Formula is revised to read as follows in both places that it appears:

Appendix I to Part 305—Heating Performance and Cost for Central Air Conditioners

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$$\text{Your estimated cost} = \text{Listed annual heating cost}^* \times \frac{\text{Your electrical cost in cents per KWH}}{8.28\text{¢}}$$

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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 862

[Docket Nos. 01P-0119 and 01P-0235]

Clinical Chemistry and Clinical Toxicology Devices; Reclassification of Cyclosporine and Tacrolimus Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying cyclosporine and tacrolimus assays from class III (premarket approval) to class II (special controls). These assays are used as an aid in the management of transplant patients receiving these drugs. FDA is also identifying the guidance document entitled “Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA” as the special control the agency believes will

reasonably ensure the safety and effectiveness of these devices. This reclassification is being taken after a review of petitions submitted by Dade Behring, Inc., and Microgenics, Inc. The agency is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a class II special controls guidance entitled “Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA.”

DATES: This rule is effective October 16, 2002.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 301-594-1243.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 21, 2002 (67 FR 7982), FDA published a proposed rule to reclassify cyclosporine and tacrolimus assays after reviewing information contained in reclassification petitions submitted by Dade Behring, Inc., and Microgenics,

Inc. FDA identified the guidance document entitled “Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA” as the special control capable of providing reasonable assurance of safety and effectiveness for these devices. These assays are used as an aid in the management of transplant patients receiving these drugs. Interested persons were invited to comment on the proposed rule by April 22, 2002. FDA received two comments that were supportive of its proposed reclassification, but the comments suggested specific recommendations for changes to the guidance.

II. FDA’s Conclusions

Based on a review of the available information referenced in the preamble to the proposed rule and placed on file in FDA’s Dockets Management Branch, FDA concludes that the special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document. The guidance document was revised to reflect consideration of the comments received. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a cyclosporine or tacrolimus test system will need to address the issues covered in the special