

(15 U.S.C. 2051 *et seq.*), which established the Consumer Product Safety Commission. Section 30(b) of the CPSA (15 U.S.C. 2079(b)) transferred to the Commission the authority formerly exercised by DOC and other agencies under the FFA.

In 1974, the Commission issued regulations for the labeling and advertising of children's sleepwear in sizes 0 through 6X. 16 CFR Part 1615, Subpart B. See the Federal Register notice of February 7, 1974 (39 FR 4852). These regulations required noncomplying children's sleepwear manufactured between July 29, 1972, and July 29, 1973, to be labeled with the statement "Flammable (Does Not Meet U.S. Department of Commerce Standard DOC FF 3-71). Should not be worn near sources of fire." 16 CFR 1615.31(b)(3). This is the same statement required by section 1615.5(b) of the standard.

3. Advertising and Retail Display Requirements

The regulations issued in 1974 also required the labeling statement to be included in direct mail advertisements and catalogs for noncomplying children's sleepwear manufactured between July 29, 1972, and July 29, 1973. 16 CFR 1615.31(c).

In 1974, the Commission amended the regulations by issuing additional requirements for labeling and requirements for recordkeeping and retail display of sleepwear in sizes 0 through 6X. See the Federal Register notice of April 14, 1975 (40 FR 16654). The Commission required any person who sold noncomplying sleepwear at retail to segregate it from complying sleepwear and to identify noncomplying sleepwear in sizes 0 through 6X by a sign stating: "Flammable. Does Not Meet Standard for the Flammability of Children's Sleepwear (DOC 3-71)." 16 CFR 1615.31(d). Complying sleepwear in sizes 0 through 6X sold at the same location as noncomplying sleepwear was required to be identified by a sign stating "Flame Resistant. Complies With Standard for Flammability of Children's Sleepwear." *Id.*

B. Revocation

Noncomplying sleepwear in sizes 0 through 6X has not been legally manufactured since July 29, 1973. Noncomplying sleepwear subject to the labeling, advertising, and retail display requirements described above is not now offered for sale and will not be offered for sale in the future. For this reason, the Commission is revoking (i) the labeling requirements in section 1615.5(b) of the standard and in section 1615.31(b)(3) of the enforcement

regulations, (ii) the requirements for advertising of noncomplying sleepwear in section 1615.31(c) of the enforcement regulations, and (iii) the requirements for retail display of noncomplying and complying sleepwear in section 1615.31(d) of those regulations.

Generally, the Administrative Procedure Act (APA) (5 U.S.C. 553) requires agencies to publish a notice of proposed rulemaking and provide opportunity for public comment before issuing or revoking a regulation. However, the APA provides at 5 U.S.C. 553(b)(B) that the requirement for a notice of proposed rulemaking is not applicable when the agency finds for good cause that notice of proposed rulemaking and public participation are "impracticable, unnecessary, or contrary to the public interest."

The Commission finds for good cause that notice of proposed rulemaking and public participation are unnecessary because no sleepwear in sizes 0 through 6X offered for sale now or that will be offered for sale in the future is subject to the requirements of 16 CFR sections 1615.5(b), 1615.31(b)(3), 1615.31(c), or 1615.31(d). The rules being revoked have no effect on the rights or duties of any persons who manufacture, sell, or purchase sleepwear in sizes 0 through 6X. Providing notice of proposed rulemaking and opportunity for submission of written comments on the proposal would be a meaningless procedure in this case.

The APA also requires at 5 U.S.C. 553(d) that a substantive rule must be published at least 30 days before its effective date unless the agency finds for good cause that such delay is not needed. Again, because no sleepwear in sizes 0 through 6X offered for sale now or in the future is or will be subject to the rules being revoked, the Commission finds for good cause that a delayed effective date is unnecessary. Consequently, this revocation shall become effective immediately.

C. Conclusion

Under the authority of section 553 of the Administrative Procedure Act and sections 4 and 5 of the Flammable Fabrics Act, the Commission hereby amends title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Part 1615 as follows:

PART 1615—[AMENDED]

Subpart A—[Amended]

1. The authority for Part 1615, Subpart A, continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569-70; 15 U.S.C. 1193.

§ 1615.5 [Removed and reserved]

2. Section 1615.5(b) is removed and reserved.

Subpart B—[Amended]

3. The authority for Part 1615, Subpart B, continues to read as follows:

Authority: Sec. 5, 67 Stat. 112, as amended, 81 Stat. 570; 15 U.S.C. 1194.

§ 1615.31 [Removed and reserved]

4. Sections 1615.31(b)(3), (c), and (d) are removed and reserved.

(5 U.S.C. 553; 15 U.S.C. 1193, 1194)

Dated: December 15, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 96-422 Filed 1-11-96; 2:00 pm]

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16 CFR Part 1616

Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14

AGENCY: Consumer Product Safety Commission.

ACTION: Revocation of rules.

SUMMARY: The Commission revokes rules prescribing requirements for labeling and retail display of children's sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978. The Commission is revoking these rules because no items of children's sleepwear offered for sale now or in the future is or will be subject to the rules' requirements.

EFFECTIVE DATE: January 16, 1996.

FOR FURTHER INFORMATION CONTACT: Allen F. Brauning, Attorney, Office of the General Counsel, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0980, extension 2216.

SUPPLEMENTARY INFORMATION:

A. Background

1. Flammability Standard

In 1974, the Consumer Product Safety Commission issued the Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 under the authority of the Flammable Fabrics Act (FFA) (15 U.S.C. 1193). See the Federal Register notice of May 1, 1974 (39 FR 15210). The standard is codified at 16 CFR Part 1616, Subpart A, and prescribes a flammability test for children's sleepwear garments and fabrics intended for use in those garments to protect children from unreasonable risks of burn deaths and injuries.

2. Labeling Requirements

The flammability standard became effective on May 1, 1975, and is applicable to sleepwear in sizes 7 through 14 manufactured after that date. Sleepwear in sizes 7 through 14 manufactured before the effective date of the standard is not subject to the standard, and could be sold after May 1, 1975, without violating the standard or the FFA. To help consumers identify sleepwear in sizes 7 through 14 manufactured to comply with the standard, the Commission required complying sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978, to be labeled with the statement: "Flame-resistant, U.S. Standard FF 5-74." 16 CFR 1616.6(b).

In 1975, the Commission issued regulations for labeling, recordkeeping, and retail display of children's sleepwear in sizes 7 through 14. 16 CFR Part 1616, Subpart B. See the Federal Register notice of April 1, 1975 (40 FR 14584). These regulations required complying sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978 to be labeled with the statement "Flame-resistant, U.S. Standard FF 5-74." 16 CFR 1616.31(b)(8). This is the same statement required by section 1616.6(b) of the standard.

3. Requirements for Retail Display

The regulations issued in 1975 also included a requirement to segregate complying and noncomplying sleepwear offered for sale at retail stores. The purpose of this requirement was to help consumers distinguish noncomplying sleepwear manufactured before May 1, 1975, from complying sleepwear manufactured after that date.

The Commission required any person who sold noncomplying sleepwear in sizes 7 through 14 to physically segregate it from complying sleepwear in those sizes. 16 CFR 1616.31(c). The Commission also required complying sleepwear in sizes 7 through 14 sold at the same location as noncomplying sleepwear to be identified by a sign stating: "Flame resistant. Complies with the Standard for the Flammability of Children's Sleepwear (FF 5-74)." Noncomplying sleepwear in those sizes was required to be identified by a sign stating: "Flammable. Does Not Meet Standard for the Flammability of Children's Sleepwear (FF 5-74)." *Id.*

B. Revocation

Since May 1, 1975, all sleepwear in sizes 7 through 14 must be manufactured to comply with the standard. Noncomplying sleepwear in

sizes 7 through 14 has not been legally manufactured since that date. The labeling and retail display requirements described above do not apply to sleepwear sold today or that will be sold in the future. Accordingly, the Commission is revoking (i) the labeling requirements in section 1616.6(b) of the standard and in section 1616.31(b)(8) of the enforcement regulations, and (ii) the requirements for retail display of complying and noncomplying sleepwear in section 1616.31(c) of those regulations.

Generally, the Administrative Procedure Act (APA) (5 U.S.C. 553) requires agencies to publish a notice of proposed rulemaking and provide opportunity for public comment before issuing or revoking a regulation. However, the APA provides at 5 U.S.C. 553(b)(B) that the requirement for a notice of proposed rulemaking is not applicable when the agency finds for good cause that notice of proposed rulemaking and public participation are "impracticable, unnecessary, or contrary to the public interest."

The Commission finds for good cause that notice of proposed rulemaking and public participation are unnecessary because no sleepwear in sizes 7 through 14 offered for sale now or that will be offered for sale in the future is subject to the requirements of 16 CFR 1616.6(b), 1616.31(b)(8), or 1616.31(c). The rules being revoked have no effect on the rights or duties of any persons who manufacture, sell, or purchase sleepwear in sizes 7 through 14. Providing notice of proposed rulemaking and opportunity for submission of written comments on the proposal would be a meaningless procedure in this case.

The APA also requires at 5 U.S.C. 553(d) that a substantive rule must be published at least 30 days before its effective date unless the agency finds for good cause that such delay is not needed. Again, because no sleepwear in sizes 7 through 14 offered for sale now or in the future is subject to the rules being revoked, the Commission finds for good cause that a delayed effective date is unnecessary. Consequently, this revocation shall become effective immediately.

C. Conclusion

Under the authority of section 553 of the Administrative Procedure Act and sections 4 and 5 of the Flammable Fabrics Act, the Commission hereby amends title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Part 1616 to read as follows:

PART 1616—[AMENDED]

Subpart A—[Amended]

1. The authority for Part 1616, Subpart A, continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569-70; 15 U.S.C. 1193.

§ 1616.6 [Removed and reserved]

2. Section 1616.6(b) is revoked, removed and reserved.

Subpart B—[Amended]

3. The authority for Part 1616, Subpart B, continues to read as follows:

Authority: Sec. 5, 67 Stat. 112-13, as amended, 81 Stat. 571; 15 U.S.C. 1194.

§ 1616.3 [Removed and reserved]

4. Sections 1616.31 (b)(6) and (c) are removed and reserved.

(5 U.S.C. 553; 15 U.S.C. 1193, 1194)

Dated: December 15, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 95N-0139]

RIN 0910-AA65

Medical Devices; Reclassification and Exemption From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying 111 generic types of class II devices into class I based on new information respecting such devices. FDA is also exempting the 111 generic types of devices, and 11 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. The exemptions allow