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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 00N–1520]

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency, Change From "Junior" to "Light"

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its menstrual tampon labeling regulation to change the current term for tampons that absorb 6 grams (g) and under of fluid. A tampon with 6 g or less absorbency is currently required to be labeled as ''junior''. FDA is proposing to change the term to ''light''. The term ''junior'' implies that it is only for younger, teenage women, while in fact, women of any age with light menstrual flow may find this tampon useful. FDA wishes to encourage women to use the lowest absorbency tampon appropriate for their flow to help minimize the risk of toxic shock syndrome (TSS). At present, FDA requires standardized terms to be used for the labeling of a menstrual tampon to indicate its particular absorbency. This enables consumers to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles. FDA is issuing this proposed rule under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written comments on the proposed rule by [*insert date 90 days after date of publication in the* **Federal Register**]. See section II of this document for the proposed effective date of a final rule based on this document.

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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: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 26, 1989 (54 FR 43766), FDA published a final rule which, among other things, amended its menstrual tampon labeling regulation to standardize the existing absorbency terms (junior, regular, super, and super plus) corresponding to the following four absorbency ranges: Less than 6, 6 to 9, 9 to 12, and 12 to 15 g of fluid. Recently, the agency proposed a term for 15 to 18 g absorbency tampons (''ultra''). FDA is finalizing that rule elsewhere in this issue of the **Federal Register**. When commenting on that proposed rule, several tampon manufacturers suggested changing the term for the 6 g and under tampon from ''junior'' to ''light'', because ''junior'' implies for teenagers only. These manufacturers argued that, in reality, the least absorbent tampon should be used by all women, commensurate with the amount of their menstrual flow. The age or size of a women should not be a deciding factor. The agency agrees that this term change would help woman decide which tampon they should use.

FDA is aware of literature suggesting that the lowest absorbency of tampon that is effective should be chosen, to minimize the risk of TSS. FDA believes that using the term ''light'' for low absorbency tampons (rather than ''junior'') will help women make the appropriate selection.

Tampons are currently classified into class II (special controls) (see 21 CFR 884.5460 and 884.5470). Any person who is required to register under section 510 of the act (21 U.S.C. 360) and part 807 of the regulations (21 CFR part 807) and who intends to begin the introduction or delivery for introduction into interstate commerce of a tampon for commercial distribution is required to submit a premarket notification to FDA at least 90 days before making such introduction

or delivery in accordance with section 510(k) of the act (21 U.S.C. 360(k)) and subpart E of part 807. Under § 807.87(e), a premarket notification for a device is to contain, among other things, labeling for the device.

II. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 90 days after the date of publication of the final rule in the **Federal Register**.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Any small entity that decided to enter the market with this product would incur no additional costs because of this rule. That small entity would already be required to identify the absorbency ranges of its tampons. The agency, therefore,

certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

V. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by [*insert date 90 days after date of publication in the* **Federal Register**]. 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.

VI. Paperwork Reduction Act of 1995

This proposed rule does not contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). This proposed rule requires public disclosure, on labeling, of information supplied by FDA to tampon manufacturers. Such information is not included in the definition of "collection of information" under the Paperwork Reduction Act regulation (5 CFR 1320.3(c)(3)).

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 801 be amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

2. Section 801.430 is amended by revising the table in paragraph (e)(1) to read as follows:

§ 801.430 User labeling for menstrual tampons.

* * * * *

(e) * * *

(1) * * *

Ranges of absorbency in grams[1]	Corresponding term of absorbency
6 and under	Light absorbency.
6 to 9	Regular absorbency.
9 to 12	Super absorbency.
12 to 15	Super plus absorbency.
15 to 18	Ultra absorbency.
Above 18	No term.

[1] These ranges are defined, respectively, as follows: Less than or equal to 6 grams (g); greater than 6 g up to and including 9 g; greater than 9 g up to and including 12 g; greater than 12 g up to and including 15 g; greater than 15 g up to and including 18 g; and greater than 18 g.

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Dated: 10-2-00
October 2, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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