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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 98N-0970]

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency

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 provide an absorbency term for tampons that absorb 15 to 18 grams (g) of fluid. The purpose of this proposed rule is to enable 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: Written comments on the proposed rule should be submitted 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. Written comments on the information collection requirements should be submitted by *(insert date 30 days after date of publication in the **Federal Register**)*.

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. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments regarding the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

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. The final rule did not include corresponding terms of absorbency for 15 to 18 g nor the range above 18 g of fluid. Tampon manufacturers have asserted that many women with heavy menstrual flow need higher absorbency tampons to manage their heavy menstrual flow (see 54 FR 43766 at 43769).

FDA has consulted with the Center for Disease Control on this proposed rule. Tampons with absorbency up to 18 g have been marketed in other countries with very low Toxic Shock Syndrome (TSS) rates. FDA believes that the proposed rule will not materially increase the risk of TSS for women using tampons in accordance with the labeling.

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 (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 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. Because there is no uniform labeling term for tampons that absorb 15 to 18 g of fluid, the agency is now proposing that tampons that absorb 15 to 18 g of fluid be labeled as “ultra absorbency”. The agency is specifically seeking comment on the term “ultra” for this absorbency range, and it invites

suggestions of any alternative terms. At this time, FDA is not proposing a term describing tampons with absorbency above 18 g of fluid, and does not anticipate that tampons in the above 18 g absorbency range will be considered for premarket clearance based on this proposed rule.

II. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 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 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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. Because manufacturers already are required to identify the absorbency ranges of their tampons, establishing a standardized term for tampons that absorb 15 to 18 g of fluid will impose no significant economic impact on any small

entities. The agency therefore certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

V. Request for Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing each collection of information.

At this time, FDA is seeking clearance only for the information collections that would be imposed by this proposed rule. FDA intends to seek clearance for other information collections in § 801.430 (21 CFR 801.430) in the immediate future.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of

information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency of 15 to 18 grams.

Description: These information collection requirements in this proposed rule apply to tampon manufacturers. This proposed rule would establish a standardized term of absorbency, “ultra,” for 15 to 18 g of fluid. Standardized terms already have been established for lower ranges of absorbency. Manufacturers of “ultra” absorbency tampons would be required to label the product in accordance with § 801.430. The labeling would have to be supported by design and performance specifications, as well as certain test results, including dimensions, pledget weight, absorbency by Syngyna method, adequate string attachment, and microbiological testing. The purpose of the proposed rule is to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles and choose the least absorbent tampon needed to control menstrual flow and, thus, reduce their risk of TSS.

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours	Total Operating Costs
801.430(e)(1)	2	1	2	40	80	3,200

¹ There are no capital or maintenance costs associated with this collection of information.

These estimates are based on agency communications with industry and FDA’s knowledge and experience with tampon labeling. FDA expects that only two manufacturers would revise the labels of their products to incorporate the “ultra” absorbency range of 15 to 18 g. FDA estimates that the operating costs for changes in labeling would require a one-time cost of \$1,600 per manufacturer.

FDA tentatively concludes that the labeling requirements found in § 801.430(c) and (d) are not subject to review by OMB because they do not constitute a “collection of information” under the PRA (44 U.S.C. 3501 *et seq.*). Rather, the warning statements are “public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

In compliance with the PRA (44 U.S.C 3507(d)), the agency has submitted the collection of information provisions of the proposed rule to OMB for review. Interested persons wishing to submit comments regarding the information collection requirements should do so by (*insert date 30 days after date of publication in the Federal Register*), and should direct them to the Office of Information and Regulatory Affairs, OMB, address above.

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 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 in paragraph (e)(1) by revising the table 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	Junior 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.

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

* * * * *

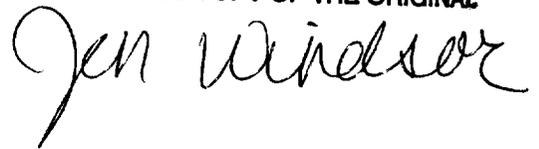
Dated: January 13, 1999

January 13, 1999



William K. Hubbard
Associate Commissioner
for Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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