

been met, including finding that the petitioner has not submitted all the information required by such clause; or

(2) A District Court of the United States in an enforcement proceeding under chapter III of the act (21 U.S.C. 301-310) has determined that the requirements of paragraph (a) of this section have not been met.

Dated: October 7, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 99-1365 Filed 1-20-99; 8:45 am]

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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 April 21, 1999. 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 February 22, 1999.

**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 April 21, 1999, 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 Burden<sup>1</sup>

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

<sup>1</sup> 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 February 22, 1999, 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 <sup>1</sup>	Corresponding term of absorbency
6 and under .....	Junior absorbency.
6 to 9 .....	Regular absorbency.
9 to 12 .....	Super absorbency.

Ranges of absorbency in grams <sup>1</sup>	Corresponding term of absorbency
12 to 15 .....	Super plus absorbency.
15 to 18 .....	Ultra absorbency.
Above 18 .....	No term.

<sup>1</sup>These 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.  
**William K. Hubbard,**  
*Associate Commissioner for Policy Coordination.*  
 [FR Doc. 99-1362 Filed 1-20-99; 8:45 am]  
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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[REG-116826-97]

RIN 1545-AW01

**Deduction for Interest on Qualified Education Loans**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and requests to videoconference the public hearing.

**SUMMARY:** This document contains proposed regulations relating to the deduction for interest paid on qualified education loans. The proposed regulations reflect changes to the law made by the Taxpayer Relief Act of 1997, the Internal Revenue Service Restructuring and Reform Act of 1998, and the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999. The proposed regulations affect taxpayers who pay interest on qualified education loans. This document also provides notice that a public hearing will be held on the proposed regulations and that persons outside the Washington, DC, area who wish to testify at the hearing may request that the IRS videoconference the hearing to their sites.

**DATES:** Written or electronically generated comments must be received by April 21, 1999. Requests to videoconference the hearing to other sites must be received by March 22, 1999.

**ADDRESSES:** Send submissions to CC:DOM:CORP:R (REG-116826-97), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station,

Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG-116826-97), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at [http://www.irs.ustreas.gov/prod/tax\\_regs/comments.html](http://www.irs.ustreas.gov/prod/tax_regs/comments.html). The IRS will publish the time and date of the public hearing and the locations of any videoconferencing sites in an announcement in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, contact John P. Moriarty, (202) 622-4950 (not a toll-free number); concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, contact Michael L. Slaughter (202) 622-7190 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Background**

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1). Section 202 of the Taxpayer Relief Act of 1997 (Pub. L. 105-34 (111 Stat. 778) (TRA 97)) added section 221 of the Internal Revenue Code to allow a deduction from gross income for certain interest paid on qualified education loans. On November 17, 1997, the IRS published Notice 97-60 (1997-46 I.R.B. 8) to provide guidance on the higher education tax incentives enacted by TRA 97, including the deduction for interest paid on qualified education loans. Section 6004(b) of the Internal Revenue Service Restructuring and Reform Act of 1998 (Pub. L. 105-206 (112 Stat. 685)) (RRA 98) and section 4003(a) of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Pub. L. 105-277 (112 Stat. 2681)) (Omnibus Act 99) made technical amendments to section 221. TRA 97 also added section 6050S to the Internal Revenue Code, which requires the filing of information returns

by certain persons who receive payments of interest that may be deductible as interest on a qualified education loan. In 1998, the IRS published two notices describing the information returns that are required under section 6050S for 1998 and 1999. On January 20, 1998, the IRS published Notice 98-7 (1998-3 I.R.B. 54), which describes the information reporting required under section 6050S for 1998. On November 16, 1998, the IRS published Notice 98-54 (1998-46 I.R.B. 25), which modified Notice 98-7 to reflect a technical amendment made by RRA 98 and extended the application of Notice 98-7, as so modified, to information reporting required under section 6050S for 1999.

**Explanation of Provisions**

Section 221 allows taxpayers who are legally obligated to pay interest on qualified education loans a federal income tax deduction for their interest payments. The deduction is an adjustment to gross income and, therefore, is available to eligible taxpayers regardless of whether they itemize deductions.

The deduction is limited to \$2,500 for taxable years beginning after 2000. For taxable years 1998, 1999 and 2000, the limits are \$1,000, \$1,500 and \$2,000, respectively. Consistent with the income limitations in section 221(b)(2), the proposed regulations provide that the deduction is phased-out for taxpayers with modified adjusted gross income between \$40,000 and \$55,000 (\$60,000 and \$75,000 for taxpayers filing a joint return) for the taxable year. For taxable years beginning after 2002, these amounts will be adjusted for inflation.

No deduction under section 221 is allowed in a taxable year to an individual who is properly claimed as a dependent on another taxpayer's federal income tax return for the taxable year. In addition, a taxpayer who is married as of the end of a taxable year is allowed a deduction under section 221 only if the taxpayer and the taxpayer's spouse file a joint return for the taxable year.

Consistent with section 221(e)(1), the proposed regulations define a *qualified*