(1) * * *

(i) Revise paragraph 1 of the Engine Fuel System section to read as follows: ''The fuel designation is General Electric (GE) Specification D50TF2, as revised. Fuel conforming to commercial jet fuel specification ASTM–D–1655, Jet A, and Jet A–1 are authorized for unlimited use in this engine. Fuels conforming to MIL–T–5624 grade JP–5 and MIL–T–83133 grade JP–8 are acceptable alternatives. The engine will operate satisfactorily with any of the foregoing fuels or any mixture thereof.'' And,

* * * * *

2. On page 34937, in the third column, paragraph (c)(1) of AD 2000–11–08 is corrected to read as follows:

* * * * *

(c) * * *

(1) Revise paragraph 1 of the Engine Fuel System section to read as follows: ''The fuel designation is General Electric (GE) Specification D50TF2, as revised. Fuel conforming to commercial jet fuel specification ASTM–D–1655, Jet A, and Jet A–1 are authorized for unlimited use in this engine. Fuels conforming to MIL–T–5624 grade JP–5 and MIL–T–83133 grade JP–8 are acceptable alternatives. The engine will operate satisfactorily with any of the foregoing fuels or any mixture thereof.'' And,

* * * * *

Issued in Renton, Washington, on October 5, 2000.

Lirio Liu Nelson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–26237 Filed 10–17–00; 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 Tampon for the ''Ultra'' Absorbency

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends its menstrual tampon labeling regulation to add the term ''ultra'' absorbency for tampons that absorb 15 to 18 grams (g) of fluid with the syngyna test. At present, FDA requires standardized terms to be used for the labeling of a menstrual tampon to indicate its particular absorbency. This rule enables consumers to compare the absorbency of one brand and style of tampon with the absorbency of other brands and styles. FDA is issuing this final rule under the Federal Food, Drug, and Cosmetic Act (the act) to ensure that labeling of menstrual tampons is not misleading. Elsewhere in this issue of the **Federal Register**, FDA is proposing to change the standardized menstrual tampon term ''junior'' to ''light''.

DATES: This rule is effective January 16, 2001.

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'') to correspond with the following four absorbency ranges: Less than 6 g; 6 to 9 g; 9 to 12 g; and 12 to 15 g of fluid, as measured by the syngyna test. The 1989 final rule did not include terms for tampons with absorbency in the 15 to 18 g range. Tampon manufacturers have asserted that many women need tampons with this higher level of absorbency to manage their heavy menstrual flow. See 54 FR 43766 to 43769.

Tampons are currently classified into class II (special controls) at 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 510(k) premarket notification for a menstrual tampon must contain, among other thing, the proposed labeling for the tampon. Section 801.430 (21 CFR 801.430) spells out the specific labeling required for tampons with 15 g or less of absorbency, including standardized terms for absorbency as determined by testing with the specified syngyna methodology. Because the regulation currently provides no uniform labeling term for tampons that absorb 15 to 18 g of fluid with the syngyna test, the agency is requiring that such tampons be labeled as ''ultra'' absorbency. FDA has recently cleared a menstrual tampons product in this absorbency range, and they are available to women in the United States. FDA believes that designating a standard term for this absorbency range will improve consumer understanding of tampons across brands and allow for better adherence to advice in the tampon labeling about toxic shock syndrome (TSS).

II. The Proposed Rule

In the **Federal Register** of January 21, 1999 (64 FR 3255 through 3257), FDA published a proposed rule to add the term ''ultra'' to describe tampons with a 15 to 18 g absorbency as measured by the syngyna test. The 90-day comment period closed on April 21, 1999.

The agency received nine comments from individuals, tampon manufacturers, one trade association, and one from a member of the U.S. Congress. Besides comments specific to use of the term ''ultra'', other comments addressed FDA's 1995 draft guidance document on the preparation of 510(k) premarket notifications for menstrual tampons (Ref. 1). Several comments recommended changing the currently used term for tampon absorbency less than 6 g, from ''junior'' to ''light''. A summary of the written comments and FDA's response to the comments is provided in section III of this document.

III. Response to Comments

1. Two comments from manufacturers supported the term ''ultra''. They noted that the term ''ultra'' is defined in Webster's Dictionary (and others) as ''going beyond what is usual or ordinary'' and ''going beyond others''. These comments also noted that menstrual tampons with this absorbency are called ''Ultra Plus'' in Canada. Comments from two other manufacturers did not favor the term ''ultra'' for this tampon absorbency. They argued that ''ultra'' implies the product is more compact in size, more concentrated, more environmentally sound, or possibly superior. The comments noted that ''ultra'' is a proprietary term carrying one or more of these meanings for a variety of other household products, such as dishwashing detergents and sanitary napkins. These manufacturers proposed the terms ''extra'' or ''extra plus''.

FDA concludes that the term ''Ultra'' is suitable to identify the absorbency of tampons in the range of 15 to 18 g. FDA

believes that the term ''Ultra'' fits more clearly within the current scheme of tampon absorbency terminology than the terms ''extra'' or ''extra plus''. The term ''ultra'' better conveys to the consumer absorbency abilities that are beyond ''Super'' and ''Super Plus'' and is less confusing to consumers than the terms ''extra'' or ''extra plus''.

Manufacturers must now define this absorbency in their labeling along with the other absorbency categories to help consumers understand the meaning of this new term. As before, labeling will continue to be required to inform consumers that they should use the lowest absorbency suitable for their needs, as well as alternating use of tampons with use of menstrual pads. FDA does not permit manufacturers to promote tampons for a wear time longer than 8 hours.

2. Five comments suggested changes in tampon labeling related to the wording of the consumer information on TSS. At present, under § 801.430(d)(2), the tampon labeling regulation requires that TSS incidence be reported in the package insert as 1 to 17 cases of TSS per 100,000 menstruating women and girls per year. These five comments requested that this labeling be revised to reflect more recent data that indicate the rate of TSS has declined. There were also various comments on FDA's draft guidance document on preparing 510(k) premarket notifications on menstrual tampons, dated May 25, 1995 (Ref. 1).

These comments were beyond the scope of the proposed rule. FDA recognizes that TSS incidence in the United States has dropped since this labeling regulation was issued in 1989. See response to comment number 6. FDA will consider these suggestions for revisions to the labeling regulation to update the TSS incidence information. Regarding the second set of comments, FDA is currently working to improve the 1995 510(k) guidance document, and the suggested changes will be considered during that process. FDA intends to issue a draft updated guidance document within a few months.

3. Five comments suggested changing the absorbency term ''junior'', used for tampons with the lowest absorbency (less than 6 g), to ''light''. They suggested that the term ''junior'' implied such tampons were only for young teenagers.

This comment also was beyond the scope of this rulemaking. However, FDA agrees that the term ''light'' is more appropriate than ''junior'' for tampons with absorbency less than 6 g. A proposed rule to change the term ''junior'' to ''light'' appears elsewhere in this issue of the **Federal Register**.

4. One comment asked why FDA did not propose a new term for tampon absorbency in the 15 to 18 g range when the other terms were issued in the regulation in 1989.

The intent of the 1989 regulation was to standardize terms currently in use so that consumers had clear information to make the best choices regardless of which brand they purchased. Although the absorbencies varied across brands, most manufacturers had no more than four different absorbencies of tampons on the market. Most companies chose to modify their products to match the standardized absorbency categories and keep the established terms. Immediately prior to issuance of the labeling regulation in 1989, only one marketed tampon was in the 15 to 18 g range. The manufacturer of this tampon chose to reduce its absorbency to 12 to 15 g and continue to use the term ''super plus''. In the preamble to the final regulation standardizing absorbency terms, FDA stated that anyone who wished to market a tampon that absorbs more than 15 g of fluid would be required to submit a 510(k). The agency would then determine whether the labeling submitted for the device was appropriate and whether the tampon required premarket approval under section 515 of the act (21 U.S.C. 360e). FDA did receive and clear a 510(k) for such a product earlier this year.

5. One comment asked how FDA would institute monitoring procedures for tracking the potential risk of increase in TSS cases.

FDA requires laboratory testing for all tampon products, as appropriate, depending on changes to materials or design. The agency already has in place Mandatory Device Reporting (MDR) requirements for manufacturers to identify and monitor reports of serious events related to device use, including menstrual TSS. In 510(k) premarket notifications, manufacturers of tampons with 15 to 18 g absorbency will provide FDA with their specific plans for monitoring trends in TSS complaints with use of their own tampon brands. The manufacturer of the product already cleared has such a plan in place. In the postmarket setting and as part of its regular MDR Program and User Facility Reporting Program, FDA will actively review any reports received on adverse events, as well as the Centers for Disease Control and Prevention (CDC) reports on menstrual-TSS.

CDC has tracked TSS reports in the United States for 20 years, and produces periodic morbidity/mortality reports. CDC recently has published a TSS surveillance update, reviewing reports from 1979 to 1996 (Ref. 2). These reports show a marked drop in TSS cases in the early 1980's with a relatively flat, extremely low number of TSS reports since approximately 1986. For instance, in 1996, there were five definite and four probable menstrual-related TSS cases reported to CDC.

The agency also notes that tampons with an absorbency as high as 18 g are currently marketed in other countries with very low TSS rates (Ref. 3). It appears that a number of factors may play a role in the etiology and risk of menstrual-related TSS, including tampon materials, continuous tampon use versus alternating use between tampons and menstrual pads, the presence of oxygen in the vaginal environment, and awareness of TSS symptoms and seeking early treatment. Standardized absorbency terms are intended to minimize the risk of menstrual-TSS with tampon use. This rule is consistent with purpose of the 1989 regulation, which is to ensure that standardized labeling gives women the information they need to make appropriate choices among all brands. FDA does not believe that this final rule will increase the risk of TSS for women who use tampons in accordance with the labeling.

6. One comment asked about the steps that might be taken to improve consumer decisionmaking about choosing the appropriate tampon absorbency.

FDA agrees that women should have a good understanding about tampon absorbency in order to make the best possible choice when purchasing tampons. In the United States, there are several public awareness initiatives in place. For nearly 20 years, FDA, CDC, and tampon manufacturers have all played a part in this process. Education programs at the local level have been contributing partners, as well. FDA believes that the current low TSS rates in the United States are a reflection of these highly effective public awareness initiatives. FDA expects that these programs, coupled with good tampon labeling, will ensure continued good choice patterns among tampon users in the United States.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30 (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.

V. Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is consistent with the regulatory philosophy and principles identified in 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. There currently are no small entities marketing a tampon of this absorbency. Any small entity that decided to enter the market with this product would incur no additional costs because of this rule because the small entity would already be required to identify the absorbency ranges of its tampons.

The agency therefore certifies that the final 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 final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final 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 (the PRA) (44 U.S.C. 3501–3520). Although the agency submitted the proposed labeling for public comment as an information collection in the proposed rule, FDA now concludes that the labeling requirement is not subject to review by OMB because it does not constitute a ''collection of information'' under the PRA. Rather, the proposed labeling is a ''public disclosure 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)).

VIII. References

The following references have been placed on display in the Docket Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Guidance for the Content of Premarket Notifications for Menstrual Tampons (draft, May 25, 1995).

2. Hajjeh, R. A., A. Reingold, A. Weil, K. Shutt, A. Schuchat, and B. Perkins, ''Toxic Shock Syndrome in the United States: Surveillance Update, 1979–1996,'' *Emerging Infectious Diseases*; vol. 5, no. 6, pp. 807–810, November/December 1999.

3. TSS rates in Canada, U.K., Germany—where 15 to 18 g tampons are already available, Medical Affairs and Regulatory Affairs at Personal Products Co. at Skillman, NJ.

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 Drug, 21 CFR part 801 is 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.

[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.

* * * * *

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–26248 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 00P–1280]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Triiodothyronine Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for the triiodothyronine test system with certain limitations. This rule will exempt from premarket notification the triiodothyronine test system intended for measuring the hormone triiodothyronine in serum and plasma. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Action of 1997 (FDAMA).

DATES: This rule is effective October 18, 2000.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices, and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, and Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. The FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976, (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is substantially equivalent within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

On April 26, 2000, FDA received a petition requesting an exemption from premarket notification for the triiodothyronine test system. The triiodothyronine test system is currently classified under 21 CFR 862.1710. In the **Federal Register** of July 11, 2000 (65 FR 42706), FDA published a notice announcing that this petition had been received and provided an opportunity for interested persons to submit comments on the petition by August 10, 2000. FDA received no comments. FDA has reviewed the petition and has determined that the triiodothyronine test system intended for measuring the hormone triiodothyronine in serum and plasma does meet the criteria for exemption from the notification requirements. This is the only type of triiodothyronine test system of which FDA presently has any knowledge. The exemption is limited to triiodothyronine test systems of the type described and is also subject to the general limitations on exemptions from premarket notification for clinical chemistry and clinical toxicology devices as described in 21 CFR 870.9. For example, the exemption will not apply to devices of this type that present new indications, novel designs, or alternative materials. The exemption also will not apply if the