The term labeling of menstrual tampons is not required to be labeled as absorbency of one brand and style of tampons 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 tampons are labeled 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 rule enables women to compare the absorbency of one brand and style of tampons 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 the absorbency terms are acceptable in both the United States and Canada. Both companies recommended agency harmonization with the Canadian requirements so that the same tampon absorbency terms are acceptable in both the United States and Canada. The agency has determined under 21 CFR 25.30(h) and (k) that this action 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 for this product would incur no additional costs because of this rule, as that entity would already be required to identify the absorbency ranges of its tampons. Because this rule imposes minimal costs, the agency 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, which includes an assessment of anticipated costs and benefits, before proposing any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is $110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to amend the menstrual tampon labeling regulation changing the current absorbency term “junior” to “light” to improve consumer understanding of tampon absorbency rates. All manufacturers of menstrual tampons with an absorbency range of less than or equal to 6 g will have to change their package labels and any other labeling using the term “junior” in reference to these products. This is a minor label change because it only requires changing one word on the labeling and will not affect label formatting or the space requirements. Manufacturers should incur minor or no incremental costs as a result of this rule because they will have 18 months in which to implement the changes and the change can be incorporated when new labels are ordered. The 18-month implementation period should also allow manufacturers to deplete their current label inventory.

The Small Business Administration (SBA) classifies a medical device entity as “small” if it has fewer than 500 employees. There are about 10 domestic manufacturers that will be affected by this rule, 5 of which meet SBA’s definition of a small entity. Frequent relabeling is a cost of doing business in the consumer health products market. Someone will be able to incorporate this labeling change at no additional cost when making other voluntary label changes. The incremental cost of a minor label change such as this is between $600 and $3,000, depending on the type of packaging and printing method. A manufacturer will incur this cost for each individual package size it markets that contains tampons with an absorbency rate of 6 g or less. The incremental cost to relabel is less than 1 percent of the small entities’ product revenues. Therefore, the final rule will not have a significant economic impact on small entities.

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 (44 U.S.C. 3501–3520). This rule requires tampon manufacturers to provide specific wording supplied by FDA on their labeling. 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 authority delegated to the Commissioner of Food and Drugs, 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:


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

<table>
<thead>
<tr>
<th>Ranges of absorb-ency in grams¹</th>
<th>Corresponding term of absorbency</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 and under</td>
<td>Light absorbency</td>
</tr>
<tr>
<td>6 to 9</td>
<td>Regular absorbency</td>
</tr>
<tr>
<td>9 to 12</td>
<td>Super absorbency</td>
</tr>
<tr>
<td>12 to 15</td>
<td>Super plus absorbency</td>
</tr>
<tr>
<td>15 to 18</td>
<td>Ultra absorbency</td>
</tr>
<tr>
<td>Above 18</td>
<td>No term</td>
</tr>
</tbody>
</table>

¹These 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.


Jeffrey Shuren, Assistant Commissioner for Policy.

[FR Doc. 04–19488 Filed 8–24–04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD07–04–103]

RIN 1625–AA08

Special Local Regulations; 2004 MTV Video Music Awards, American Airlines Arena, Port of Miami, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being established for the 2004 MTV Video Music Awards at the American Airlines Arena in the Port of Miami, Florida. These regulations are necessary for the safety of life on navigable waters. The MTV Video Music Awards Boat Parade will be held on August 29, 2004, and the parade route includes the waters of the Miami Main Channel, the Miami Harbor turning basin and the American Airlines Arena Marina Basin, with the staging area at the United States Coast Guard Base. These regulations exclude non-participant vessels from entering the regulated areas, including the staging