

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. Some companies 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.

## 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 effects 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 Executive 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 (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:

**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 <sup>1</sup>	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

<sup>1</sup>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: August 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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

BILLING CODE 4160–01–S

## 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

area, parade route and arena marine basin.

**DATES:** These regulations are effective from 3 p.m. until 11 p.m. on August 29, 2004.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket, are part of docket [CGD07-04-103] and are available for inspection or copying at Coast Guard Sector Miami, 100 MacArthur Causeway, Miami Beach, Florida, 33139 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** BMC Vaughn, Coast Guard Sector Miami, Florida at (305) 535-4317.

#### **SUPPLEMENTARY INFORMATION:**

##### **Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for these regulations. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM would be contrary to public safety interests. The organizers of the event were not able to provide necessary information prior to the event and with sufficient time remaining to publish an NPRM. As the event will be held on Sunday, August 29, 2004, there is not sufficient time to allow for a notice and comment period prior to its occurrence. Additionally, numerous spectator craft and participant craft will be in close proximity to each other around the staging area, parade area and arena marine basin, compromising the safety of all vessels in the heavily congested area. For these safety reasons, it is in the public interest to have these regulations in effect during the event. Advance notifications will be made via marine information broadcasts.

For the same reasons, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

##### **Background and Purpose**

The 2004 MTV Video Music Awards will be held in Miami at the American Airlines Arena. A boat parade of award recipients will precede the award ceremony. The boat parade will be a nighttime parade of approximately 20 vessels. The vessels range in length from 20 to 100 feet. Approximately 200 spectator craft are expected to view the parade from the waterway. The parade will form in the staging area at the Coast Guard base then proceed south into the Port of Miami, Main Channel, then west into the Miami Harbor turning basin, then west into the American Airlines Arena marina basin. The regulated area

includes the staging area, parade route and arena marine basin.

##### **Discussion of Rule**

These special local regulations prohibit non-participant vessels from entering the regulated areas, which include the staging area, parade route and arena marine basin.

The staging area encompasses all waters surrounding the Coast Guard base in Miami Beach. No anchoring or entry will be permitted in the staging area.

The parade area begins at the southerly end of the staging area, then south to the Main Channel, then west into the Miami Harbor turning basin in a box formed by the following coordinates:

MTV 1 25°46'03" N, 080°08'45" W,  
MTV 2 25°46'07" N, 080°08'43" W,  
MTV 3 25°47'05" N, 080°11'02" W,  
MTV 4 25°46'57" N, 080°11'04" W,  
MTV 5 25°46'52" N, 080°10'47" W,  
and then continues west into the marine basin at the American Airlines Arena. During transit of the parade, these regulations prohibit non-participating vessels from entering the parade area, unless authorized by the Coast Guard Patrol Commander.

The regulated area at the American Airlines Arena will consist of an area marked off by buoys at the following positions:

M1 25°47'07" N, 080°11'07" W,  
M2 25°47'05" N, 080°11'01" W,  
M3 25°47'03" N, 080°10'56" W,  
M4 25°46'59" N, 080°10'52" W,  
M5 25°46'53" N, 080°10'53" W,  
M6 25°46'48" N, 080°10'56" W,  
and the bridge transiting over to Dodge Island.

These regulations prohibit non-participating vessels from entering the area, unless authorized by the Coast Guard Patrol Commander.

##### **Regulatory Evaluation**

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). These regulations will have a minimal impact on non-participant and non-spectator vessels due to the normally low volume of vessel traffic on the regulated waterways when the regulation is effective. Moreover, this rule is only in effect for 8 hours. Also,

it regulates only the waters immediately surrounding the parade vessels, and it moves with the parade vessels. Therefore, it should have a minimal impact on non-participant and non-spectator vessels.

##### **Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the regulated area from 3 p.m. to 11 p.m. on August 29, 2004. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule is for a highly publicized event and will only be in effect for 8 hours when vessel traffic normally is minimal. Any traffic that needs to pass through the regulated area will be allowed to pass with the permission of the Coast Guard Patrol Commander once the parade participants have moved further along the parade route.

##### **Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under the **FOR FURTHER INFORMATION CONTACT** section for assistance in understanding and participating in this rulemaking. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by

employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

### Collection of Information

This rule calls for no new collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

### Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

### Unfunded Mandate Reform Act

The Unfunded Mandate Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in the preamble.

### Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the

Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order, because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

### Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design or operation; test methods; sampling procedures; and related management system practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph 34(h), of the Instruction, from further environmental documentation. Under figure 2-1, paragraph (34)(h), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule.

### List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 100.35T-07-103 to read as follows:

#### § 100.35T-07-103, 2004 MTV Video Music Awards, American Airlines Arena, Port of Miami, Miami, FL.

(a) *Regulated areas.* (1) The staging area encompasses all waters surrounding the Coast Guard Island that are west of Government Cut.

(2) The parade area begins at the southerly end of the staging area, then south to the Main Channel, then west into the Miami Harbor turning basin in a box formed by the following coordinates:

MTV 1 25°46'03" N, 080°08'45" W,  
MTV 2 25°46'07" N, 080°08'43" W,  
MTV 3 25°47'05" N, 080°11'02" W,  
MTV 4 25°46'57" N, 080°11'04" W,  
MTV 5 25°46'52" N, 080°10'47" W,

and then continues west into the marina basin at the American Airlines Arena.

(3) The marine basin regulated area at the American Airlines Arena will consist of an area marked off by buoys in the following positions:

M1 25°47'07" N, 080°11'07" W,  
M2 25°47'05" N, 080°11'01" W,  
M3 25°47'03" N, 080°10'56" W,  
M4 25°46'59" N, 080°10'52" W,  
M5 25°46'53" N, 080°10'53" W,  
M6 25°46'48" N, 080°10'56" W,

and the bridge transiting over to Dodge Island.

(b) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Sector Miami, Florida.

(c) *Special Local Regulations.* (1) *Staging area.* Entry or anchoring in the staging area by nonparticipating vessels is prohibited, unless authorized by the Patrol Commander.

(2) *Parade route.* During the parade, non-participating vessels are prohibited from entering or anchoring in the parade area, unless authorized by the Patrol Commander.

(3) *Arena marine basin.* The American Airlines Arena has a marine

basin to the northeast of the main facilities. This basin will be used to moor various spectator, participant and entertainment vessels. Entry or anchoring in the arena marine basin by nonparticipating vessels is prohibited, unless authorized by the Patrol Commander.

(d) *Effective period:* This section is effective from 3 p.m. until 11 p.m. on August 29, 2004.

Dated: August 16, 2004.

**D.B. Peterman,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.*

[FR Doc. 04-19451 Filed 8-24-04; 8:45 am]

**BILLING CODE 4910-15-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[VA159-5083a; FRL-7805-7]

#### Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revision of Flow Control Date in Nitrogen Oxides Budget Trading Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to convert a conditional approval in the Virginia State Implementation Plan (SIP) to a full approval. As required by the conditional approval, Virginia has submitted a SIP revision that pertains to the allowance banking provisions in Virginia's Nitrogen Oxides (NO<sub>x</sub>) Budget Trading Program. The SIP revision changes the start date of flow control from 2006 to 2005. Flow control is a limitation on banked allowances that are used for compliance purposes, and is required to start in the second year of the trading program. It is triggered when the regionwide total of banked allowances exceeds a specified threshold. The year 2005 will be the second year of Virginia's NO<sub>x</sub> Budget Trading program. EPA is approving this revision to Virginia's SIP in accordance with the requirements of the Clean Air Act.

**DATES:** This rule is effective on October 25, 2004 without further notice, unless EPA receives adverse written comment by September 24, 2004. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by VA159-5083 by one of the following methods:

A. Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. E-mail: [morris.makeba@epa.gov](mailto:morris.makeba@epa.gov)

C. Mail: Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. VA159-5083. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The Federal [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

**FOR FURTHER INFORMATION CONTACT:** Marilyn Powers, (215) 814-2308, or by e-mail at [powers.marilyn@epa.gov](mailto:powers.marilyn@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 8, 2003 (68 FR 40520), EPA published a final rulemaking notice (FRN) for the Commonwealth of Virginia. The FRN approved Virginia's NO<sub>x</sub> Budget Trading Program, with the exception of its NO<sub>x</sub> allowance banking provisions, which EPA conditionally approved. EPA's rationale for approving Virginia's NO<sub>x</sub> Budget Trading Program while conditionally approving the program's allowance banking provisions were provided in the November 12, 2002 (67 FR 68542) notice of proposed rulemaking (NPR), and discussed in detail in EPA's response to public comments in the FRN and will not be restated here. The terms of the conditional approval required that Virginia revise its banking provisions by changing the flow control start date from 2006 to 2005, and submit the change as a SIP revision within one year from August 7, 2003, the effective date of the conditional approval.

##### II. Summary of SIP Revision

On June 23, 2004, the Virginia Department of Environmental Quality (VADEQ) submitted a formal revision to its SIP. The SIP revision pertained to Virginia's banking provision at 9 VAC 5-140-550, and changed the flow control start date from 2006 to 2005. Virginia's NO<sub>x</sub> Budget Trading Program was implemented in 2004, therefore flow control will start in the second year of the program, which is consistent with the other states subject to the NO<sub>x</sub> SIP Call. Virginia has therefore satisfied the terms of the conditional approval.

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1-1198, provides