on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

2. FAA amends Section 39.13 by adding a new airworthiness directive (AD) to read as follows:

Raytheon Aircraft Company (The Beech Aircraft Corporation previously was the holder of Type Certificate 3A15): Docket No. 99–CE–63–AD.

(a) *What airplanes are affected by this AD?* Models Beech 35–C33A, E33A, E33C, F33A, F33C, S35, V35, V35A, V35B, 36, and A36 airplanes, all serial numbers, that:

(1) are certificated in any category;

(2) incorporate a Teledyne Continental engine equipped with a turbonormalizing system; and

(3) have Tornado Alley Turbo, Inc. Supplemental Type Certificate (STC) SA5223NM and STC SE5222NM incorporated.

Note 1: Cessna 185 series airplanes could have the subject clamp installed through the incorporation of Tornado Alley Turbo, Inc. STC SE00214DE and STC SE002215DE. The FAA has determined that the cracks at the weld spots in these V-band clamps are occurring because of the specific configuration of the Raytheon airplanes. We have received no reports of service problems with the affected V-band clamps installed on Cessna 185 series airplanes.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes referenced in paragraph (a) of this AD that are on the U.S. Register must comply with this AD.

(c) *What problem does this AD address?* The actions required by this AD are intended to prevent the exhaust stack from detaching from the turbocharger due to failure of the V-band exhaust clamp. This could result in the release of high temperature gases inside the engine compartment with a consequent fire in the engine compartment.

(d) *What must I do to address this problem?* To address this problem, you must accomplish the following actions:

Actions	Compliance times	Procedures
Repetitively replace the V-band exhaust clamp, Aeroquip part number 00624–4404C375–M..	Upon accumulating 400 hours time-in-service (TIS) after incorporating Tornado Alley Turbo, Inc. STC SA5223NM and STC SE5222NM on the airplane or within the next 25 hours TIS after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 400 hours TIS..	Use the procedures in the Turbo-Flite™ 520/550 System Maintenance and Troubleshooting manual.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Rotorcraft Directorate, Special Certification Office, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Rotorcraft Directorate, Special Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0190.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* You can contact Mr. Peter Hakala, Aerospace Engineer, FAA, Rotorcraft Directorate, Special Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0190;, telephone: (817) 222–5145; facsimile: (817) 222–5785.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(1) In order for this permit to be granted, the airplane must pass the push/pull test specified in Tornado Alley Turbo, Inc., Mandatory Service Bulletin Number TAT 98–1, dated November 21, 1998.

(2) Anyone who holds at least a private pilot certificate, as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), may accomplish the push/pull test referenced in paragraph (g)(1) of this. You must make an entry into the aircraft records that shows compliance with this portion of the AD, in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

(h) *How do I get copies of the documents referenced in this AD?* You may obtain copies of the documents referenced in this AD from Tornado Alley Turbo, Inc., 300 Airport Road, Ada, Oklahoma 74820; or may examine this document at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 11, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–26712 Filed 10–17–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 00N–1520]

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency, Change From ''Junior'' to ''Light''

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 change the current term for tampons that absorb 6 grams (g) and under of fluid. A tampon with 6 g or less absorbency is currently required to

be labeled as ''junior''. FDA is proposing to change the term to ''light''. The term ''junior'' implies that it is only for younger, teenage women, while in fact, women of any age with light menstrual flow may find this tampon useful. FDA wishes to encourage women to use the lowest absorbency tampon appropriate for their flow 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 enables 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: Submit written comments on the proposed rule by January 16, 2001. See section II of this document for the proposed effective date of a final rule based on this document.

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.

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. Recently, the agency proposed a term for 15 to 18 g absorbency tampons (''ultra''). FDA is finalizing that rule elsewhere in this issue of the **Federal Register**. When commenting on that proposed rule, several tampon manufacturers suggested changing the term for the 6 g and under tampon from ''junior'' to ''light'', because ''junior'' implies for teenagers only. These manufacturers argued that, in reality, the least absorbent tampon should be used by all women, commensurate with the amount of their menstrual flow. The age or size of a women should not be a deciding factor. The agency agrees that this term change would help woman decide which tampon they should use.

FDA is aware of literature suggesting that the lowest absorbency of tampon that is effective should be chosen, to minimize the risk of TSS. FDA believes that using the term ''light'' for low absorbency tampons (rather than ''junior'') will help women make the appropriate selection.

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 of the regulations (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 (21 U.S.C. 360(k)) 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.

II. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 90 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 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 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. Any small entity that decided to enter the market with this product would incur no additional costs because of this rule. That small entity would already be required to identify the absorbency ranges of its tampons. The agency, therefore, certifies that the proposed 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 proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

V. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by January 16, 2001. 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 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 proposed rule requires public disclosure, on labeling, of information supplied by FDA to tampon manufacturers. 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 the 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 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[1]	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.

[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. 00–26249 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[MO 114–1114; FRL–6885–7]

Approval and Promulgation of Implementation Plans; State of Missouri; Designation of Areas for Air Quality Planning Purposes; Dent Township

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve a State Implementation Plan (SIP) revision submitted by the state of Missouri and Missouri's request to redesignate the lead nonattainment area in western Iron County, Missouri, to attainment of the National Ambient Air Quality Standards (NAAQS). EPA proposes to approve the maintenance plan for this area including a consent order which was submitted with the redesignation request, and also proposes to approve the revision to Missouri's Restriction of Emissions of Lead From Specific Lead Smelter-Refinery Installations rule which ensures the permanent and enforceable emission reductions by clarifying the emissions limits for the Doe Run Resource Recycling Facility, and removes the text which could have allowed this facility to resume operation as a primary smelter.

In the final rules section of today's **Federal Register**, EPA is approving the state's SIP revision and redesignation request as a direct final rule without prior proposal because the Agency views this as a noncontroversial action and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed action must be received in writing by November 17, 2000.

ADDRESSES: Comments may be mailed to Kim Johnson, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Kim Johnson at (913) 551–7975.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the rules section of today's **Federal Register**.

Dated: September 27, 2000.

Dennis Grams,

Regional Administrator, Region 7.

[FR Doc. 00–26502 Filed 10–17–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

OPPTS–50639; FRL–6745–5

RIN 2070–AD43

Perfluorooctyl Sulfonates; Proposed Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the following chemical substances: Perfluorooctanesulfonic acid (PFOSA) and certain of its salts (PFOSS), perfluorooctanesulfonyl fluoride (PFOSF), certain higher and lower homologues of PFOSA and PFOSF, and certain other chemical substances, including polymers, that contain PFOSA and its homologues as substructures. All of these chemical substances are referred to collectively in this proposed rule as perfluorooctyl sulfonates, or PFOS. This proposed rule would require manufacturers and importers to notify EPA at least 90 days before commencing the manufacture or import of these chemical substances for the significant new uses described in this document. EPA believes that this action is necessary because the chemical substances included in this proposed rule may be hazardous to human health and the environment. The required notice would provide EPA with the opportunity to evaluate an intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs.

DATES: Comments, identified by the docket number OPPTS–50639, are due November 17, 2000.