

the maximum extent possible. The forms and other information collection activities required for participation in the program are available electronically for downloading or electronic submission through the USDA eForms Web site at <http://forms.sc.egov.usda.gov/eforms>.

#### Federal Assistance Programs

The title and number of the Federal assistance program found in the Catalog of Federal Domestic Assistance to which this final rule applies are Commodity Loans and Loan Deficiency Payments, 10.051.

#### List of Subjects in 7 CFR Part 1434

Honey, Loan programs-agriculture, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble, 7 CFR part 1434 is amended as follows:

#### PART 1434—NONRECOURSE MARKETING ASSISTANCE LOAN AND LDP REGULATIONS FOR HONEY

■ 1. The authority citation for part 1434 continues to read as follows:

Authority: 7 U.S.C. 7931.

■ 2. Amend § 1434.8 by revising paragraphs (a) and (b)(4) to read as follows:

##### § 1434.8 Containers and drums.

(a)(1) To be eligible for assistance under this part, honey must be packed in:

- (i) CCC-approved, 5-gallon plastic containers;
- (ii) 5-gallon metal containers;
- (iii) Steel drums with a capacity not less than 5 gallons nor greater than 70 gallons, or
- (iv) Plastic Intermediate Bulk Containers (IBC's).

(2) Honey stored in plastic containers must be determined safe and secure from all possibility of contamination.

(3) Honey storage containers used for these purposes must meet requirements of the Federal Food, Drug and Cosmetic Act, as amended and other specified requirements, as determined by CCC and must be generally fit for the purpose for which they are to be used.

(4) CCC-approved 5-gallon plastic containers must hold approximately 60 pounds of honey. The containers must be free and clear of leakage and punctures and of suitable purity for food contact use and meet food storage standards as provided by CCC. Plastic containers must be new or previously used only to store honey. Plastic containers previously used to store chemicals, pesticides, or any other

product or substance other than honey are ineligible for honey storage. The handle of each container must be firm and strong enough to permit carrying the filled container. The cover opening must not be damaged in any way that will prevent a tight seal. Containers that have been punctured and resealed will not be acceptable;

(5) The 5-gallon metal containers must hold approximately 60 pounds of honey, and must be new, clean, sound, uncased, and free from appreciable dents and rusts. The handle of each container must be firm and strong enough to permit carrying the filled container. The cover and container opening must not be damaged in any way that will prevent a tight seal. Containers that are punctured or have been punctured and resealed by soldering will not be acceptable; and

(6) The steel drums must be an open type and filled no closer than 2 inches from the top of the drums. Drums must be new or must be used drums that have been reconditioned inside and outside. Drums must be clean, treated inside and outside to prevent rusting, fitted with gaskets that provide a tight seal and have an inside coating suitable for honey storage.

(7) IBC's are bulk containers with a polyethylene inner bottle and a galvanized steel protective cage, a capacity of either 275 or 330 gallons, and are reusable. IBC's must be clean, sound and provide a tight seal.

(b) \* \* \*

(4) Containers that do not meet the specified requirements of paragraph (a) of this section or other CCC specifications or requirements.

\* \* \* \* \*

Signed in Washington, DC, on July 6, 2004.

James R. Little,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 04-19401 Filed 8-24-04; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 74

[Docket No. 1987C-0023]

#### Listing of Color Additives Subject to Certification; D&C Black No. 2; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of July 28, 2004 (69 FR 44927). The final rule amended the color additive regulations to provide for the safe use of D&C Black No. 2 (a high-purity furnace black, subject to FDA batch certification) as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. The action was in response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association. The final rule published with inadvertent errors. This document corrects those errors.

**DATES:** See the first correction under **SUPPLEMENTARY INFORMATION**.

#### FOR FURTHER INFORMATION CONTACT:

Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3423.

**SUPPLEMENTARY INFORMATION:** In the FR Doc. 04-17153, appearing on page 44927, in the **Federal Register** of July 28, 2004, the following corrections are made:

■ 1. On page 44927, in the third column, the section entitled “**DATES**,” is corrected to read:

**DATES:** This rule is effective August 30, 2004. Submit objections and requests for a hearing by August 27, 2004. See section IX of this document for information on the filing of objections.

■ 2. On page 44929, in the third column, under the section “**Objections**,” the heading and paragraph are corrected to read:

#### IX. Objections

This rule is effective as shown in the “**DATES**” section of this document; except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the

objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

Dated: August 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-19398 Filed 8-24-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 801

[Docket No. 2000N-1520]

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

**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 change the current term for tampons that absorb 6 grams (g) and under of fluid. A tampon with absorbency of 6 g or less is currently required to be labeled as "junior". FDA is changing the term "junior" to "light". The term "junior" implies that the tampon is only for younger or teenage women when, in fact, it may be appropriate for women of any age with light menstrual flow. FDA encourages 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 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 labeling of menstrual tampons is not misleading.

**DATES:** This rule is effective February 27, 2006.

**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. FDA announced the availability of the term for 15 to 18 g absorbency tampons ("ultra") in the **Federal Register** of October 18, 2000 (65 FR 62317). When commenting on that proposed rule, manufacturers argued that women should use the least absorbent tampon necessary and that the amount of their menstrual flow, not the age or size of a woman, should determine the absorbency of the tampon she should use. FDA is also aware of literature suggesting that, to minimize the risk of TSS, the lowest absorbency of tampon that is effective should be chosen.

##### II. The Proposed Rule

In the **Federal Register** of October 18, 2000, FDA published a proposed rule to amend its tampon labeling regulation to change the current term for tampons that absorb 6 g and under of fluid. FDA proposed this change because it believes that changing the standard term for this absorbency range from "junior" to "light" will improve consumer understanding of tampons across brands, and it will make it easier for women to adhere to advice in the tampon labeling about reducing the risk of TSS. The 90-day comment period closed on January 16, 2001. The agency received comments from two tampon manufacturers.

##### III. Response to Comments

(Comment 1) Both companies supported FDA's proposal to change the absorbency term for tampons that absorb 0 to 6 g of fluid from "junior" to "light". They agreed with the agency's position that this change will reduce the mistaken impression held by many women that the term "junior" means the tampons are intended only for younger or teenage women, rather than referring to the amount of menstrual flow.

Comments from both manufacturers noted that the proposed effective date of 90 days after publication of the final rule in the **Federal Register** would not allow sufficient time for manufacturers to deplete their inventories of existing packaging materials or revise labeling

and artwork on retail packages. Both companies recommended the agency allow a 24-month period following publication of the final rule in the **Federal Register** during which tampons that absorb 6 g or less of fluid could be sold with either a "junior" or a "light" designation. One company recommended that only those tampons which have a valid date code within 24 months of publication of the final rule in the **Federal Register** be allowed to carry the "junior" designation.

(Response) Based on available information regarding labeling of these devices, FDA has concluded that 18 months after publication of the final rule should be sufficient for manufacturers to implement the "light" absorbency designation on their product package labeling.

(Comment 2) Comments from the manufacturers also suggested that the change to "light absorbency" in the U.S. tampon labeling regulation will result in inconsistency with current Canadian tampon labeling requirements. 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.

(Response) The agency intends to work with the Canadian device authorities to harmonize required absorbency terms for tampons.

##### IV. 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.

##### V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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. In addition, the final rule is not a significant regulatory action as defined by the Executive order