DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 99F–2533]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Change in Specifications for Gum or Wood Rosin Derivatives in Chewing Gum Base

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for a change in the softening point specifications of currently listed gum or wood rosin derivatives and to provide for their safe use as plasticizing materials (softeners) in chewing gum base. This action is in response to a petition filed by Hercules, Inc.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3072.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** on August 5, 1999 (64 FR 42699), FDA announced that a food additive petition (FAP 9A4655) had been filed by Hercules, Inc., c/o 1001 G St. NW., Washington, DC 20001. The petition proposed to amend the food additive regulations in § 172.615 *Chewing gum base* (21 CFR 172.615) to permit a change in the softening point specifications of currently listed gum or wood rosin derivatives and provide for their safe use as plasticizing materials (softeners) in chewing gum base. More specifically, the petition proposed to eliminate the upper limits on the permissible softening point ranges for these gum or wood rosin derivatives.

The gum or wood rosin derivatives, which are the subject of this petition, include glycerol ester of partially dimerized rosin, glycerol ester of partially hydrogenated gum or wood rosin, glycerol ester of polymerized rosin, glycerol ester of gum rosin, pentaerythritol ester of partially hydrogenated gum or wood rosin, and pentaerythritol ester of gum or wood rosin. Specifications for rosin derivatives conforming to this regulation include a melting point range (for glycerol ester of polymerized rosin) or a drop softening point range for other derivatives. The petitioner is proposing to modify these specifications by listing only a minimum melting point or softening point.

II. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the change in the melting point or softening point specifications for glycerol ester of partially dimerized rosin, glycerol ester of partially hydrogenated gum or wood rosin, glycerol ester of polymerized rosin, glycerol ester of gum rosin, pentaerythritol ester of partially hydrogenated gum or wood rosin, and pentaerythritol ester of gum or wood rosin is safe and that gum or wood rosin derivatives with the revised specifications will achieve their intended technical effect. Therefore, the agency concludes that the regulations in § 172.615 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

III. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the* **Federal Register**]. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.615 is amended in paragraph (a) by revising the following entries in the table under the subheading "Plasticizing Materials (Softeners)" to read as follows:

§ 172.615 Chewing gum base.

* * * * *

(a) * * *

Plasticizing Materials (Softeners)	
Glycerol ester of partially dimerized rosin	Having an acid number of 3–8, a minimum drop-softening point of 109 °C, and a color of M or paler.
Glycerol ester of partially hydrogenated gum or wood rosin	Having an acid number of 3–10, a minimum drop-softening point of 79 °C, and a color of N or paler.
Glycerol ester of polymerized rosin	Having an acid number of 3–12, a minimum melting-point of 80 °C, and a color of M or paler.
Glycerol ester of gum rosin	Having an acid number of 5–9, a minimum drop-softening point of 88 °C, and a color of N or paler. The ester is purified by steam striping.
* * * * * * *	
Pentaerythritol ester of partially hydrogenated gum or wood rosin	Having an acid number of 7–18, a minimum drop-softening point of 102 °C, and a color of K or paler.
Pentaerythritol ester of gum or wood rosin	Having an acid number of 6–16, a minimum drop-softening point of 109 °C, and a color of M or paler.
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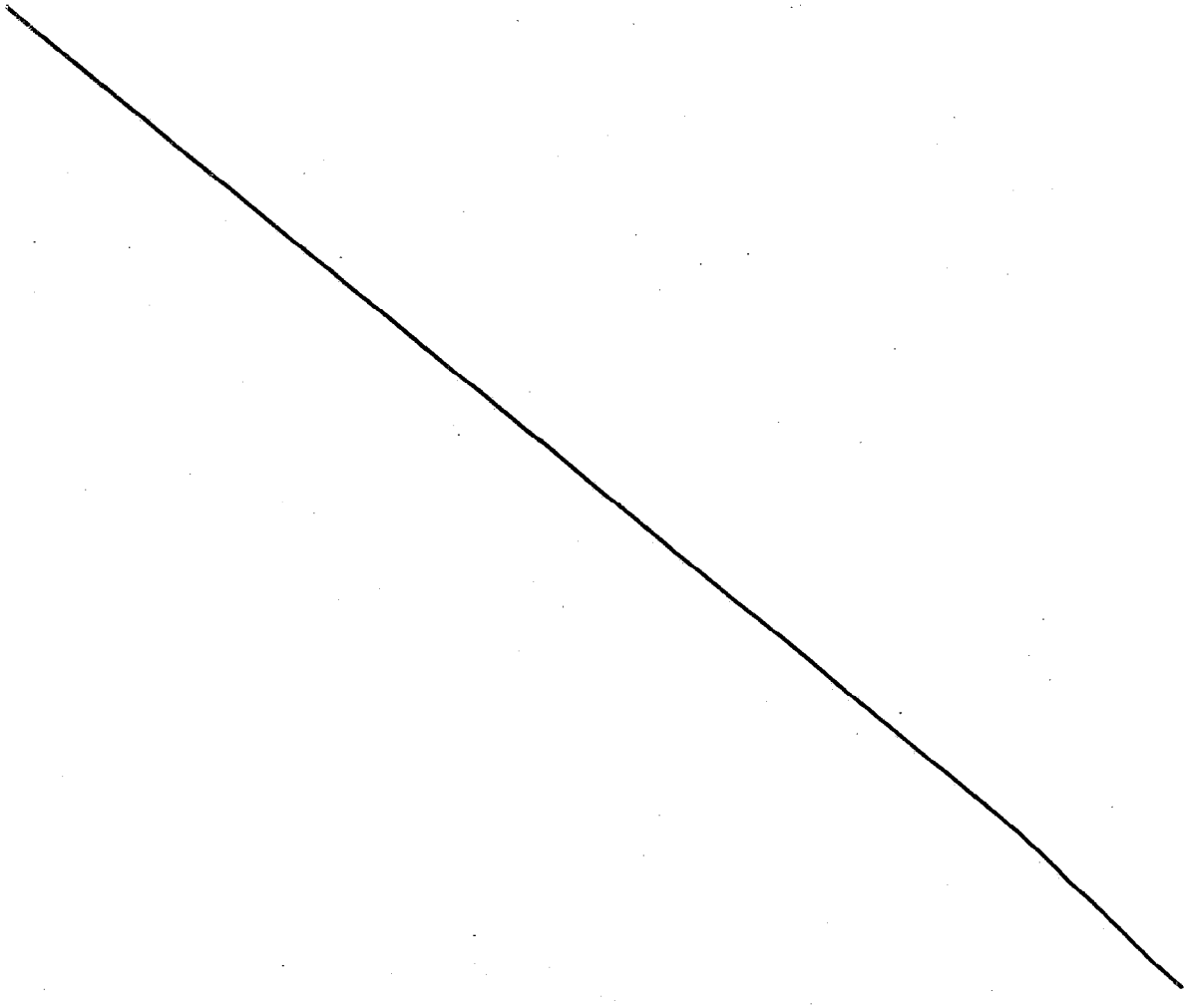

Dated: 7/9/01

July 9, 2001.

cf0126

L. Robert Lake

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Director of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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