color additives and color additive mixtures.

III. Analysis of Impacts

FDA has examined the impacts of the interim final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandate Reforms Flexibility Act (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 interim final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the interim final 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. The entire cost of this fee increase would be approximately $849,626 per year and would be distributed amongst approximately 23 companies who would pay an increased fee that is proportional to the number of pounds of color that they certify. The great majority of these costs will be borne by a few firms that have a dominate share of the color certification market. These firms that have the largest shares of the market would pay most of these fees. In addition, by the Small Business Administration (SBA) standards, all of the affected manufacturers of color additives are considered large. Thus, the agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

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 $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Environmental Impact

The agency has determined under 21 CFR 25.22(a) 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. Opportunity for Public Comment

Under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e), FDA finds that providing for notice and public comment before the establishment of these fees, and for revising the basis on which these fees are calculated, is contrary to the public interest. It is necessary to implement the fee increase as soon as possible to preserve adequate funds for the program. A delay could result in the fund being exhausted before the end of the fiscal year. The agency believes, however, that it is appropriate to invite and consider public comments on these requirements.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic copies or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 80

Color additives, Cosmetics, Drugs, 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 80 is amended as follows:

PART 80—COLOR ADDITIVE CERTIFICATION

■ 1. The authority citation for 21 CFR part 80 continues to read as follows:

Authority: 21 U.S.C. 371, 379e.

■ 2. Section 80.10 is amended by revising paragraphs (a) and (b) to read as follows:

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (j)(2) shall be $0.35 per pound of the batch covered by such requests, but no such fee shall be less than $224.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—$35.

(2) Over 100 pounds but not over 1,000 pounds—$35 plus $0.05 for each pound over 100 pounds.

(3) Over 1,000 pounds—$89 plus $0.02 for each pound over 1,000 pounds.

* * * * *

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6155 Filed 3–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2003F–0471]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Glycerol Ester of Gum Rosin

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 the safe use of glycerol ester of gum rosin (GEGR) to adjust the density of citrus oils used in the preparation of beverages. This action is in response to a petition filed by T&R Chemicals, Inc.

DATES: This rule is effective March 29, 2005. Submit written or electronic objections and requests for a hearing by April 28, 2005.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2003F–0471, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*.

Follow the instructions for submitting comments on the agency Web site.

- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2003F–0471 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of October 17, 2003 (68 FR 59794), FDA announced that a food additive petition (FAP 3A4749) had been filed by T&R Chemicals, Inc., c/o The Environ Health Sciences Institute, 4350 North Fairfax Dr., suite 300, Arlington, VA 22203. The petition proposed to amend the food additive regulations in part 172 (21 CFR part 172) to provide for the safe use of GEGR to adjust the density of citrus oils used in the preparation of beverages.

The proposed additive is intended to substitute for glycerol ester of wood rosin (GEWR). GEWR is currently permitted under § 172.735 for use in adjusting the density of citrus oils used in the preparation of beverages at a level not to exceed 100 parts per million (ppm) of the finished beverage. GEGR would be used at the same level as GEWR. In evaluating this petition, the agency reviewed data and information concerning: (1) The chemical composition of GEGR in comparison with that of GEWR, (2) the process used to manufacture GEGR, (3) physicochemical properties of GEGR compared to those of GEWR, (4) conformance of GEGR with the specifications in § 172.735 for GEWR, (5) the functional equivalence of GEGR to GEWR, and (6) relevant safety information.

Based on its evaluation, the agency has determined that GEGR is chemically similar to GEWR, such that any increase in the estimated daily intake (EDI) of the individual resin acids and resin acid esters that are the major components of both GEGR and GEWR from the petitioned use of GEGR would be insignificant and of no toxicological concern. The agency concludes that the petitioned use of GEGR as a substitute for GEWR to adjust the density of citrus oils used in the preparation of beverages at a level not to exceed 100 ppm of the finished beverage is safe, the additive will achieve its intended technical effect, and therefore, § 172.735 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 (see **FOR FURTHER INFORMATION CONTACT**). 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.

II. Response to Comments

During the course of FDA's evaluation of FAP 3A4749, the agency received one comment on the petition. This comment objects to the petitioner's claim that GEGR and GEWR are chemically equivalent. The comment points to purported differences in raw material sourcing and processing, compositional differences and variation in gum rosin, and differences occurring during the esterification process due to variations in the resin acid content. The comment also challenges the analytical methodology (i.e., saponification followed by gas chromatographic analysis) used by the petitioner in comparing GEGR and GEWR. The comment further objects to the petitioner's reliance on safety data which support the use of GEWR as the basis for establishing the safety of GEGR, on the grounds that such use of unpublished information furnished previously to FDA by another person was not authorized as required by § 171.1(b).

While FDA agrees that there are differences in raw material sourcing and processing for GEGR and GEWR, FDA has concluded that the compositions of these two substances are so similar that any differences are not of toxicological concern for the petitioned use. FDA also agrees there will be variability in the composition of the rosins depending on the source and even from the same source due to differences in climate and soil conditions (Ref. 1). However, this natural variability does not result in a qualitatively different composition of the rosin but rather a typical range of values for the individual components of the rosin. Because of source variability and different climates and soils, the composition of GEGR will vary from batch to batch, although its general composition will fall within a typical range. The composition of GEWR will vary in an analogous manner. Furthermore, this variability in the rosin composition does not result in a significant difference in the EDI for the individual resin acid components of GEGR and GEWR for the conditions of use. In addition, GEWR is characterized by its physical properties, which are specified in § 172.735. GEGR will have to conform to these same specifications.

As stated previously in this document, the comment also challenges the analytical methodology (i.e., saponification followed by gas chromatographic analysis) used by the petitioner in comparing GEGR and GEWR. The comment claims that this technique is inappropriate because it can induce isomerization of the resin acids, thereby changing the composition compared to the starting rosin. No literature references or data were provided to support this statement. In addition, the procedure used by the petitioner included a step to decrease the amount of isomerization. The petitioner also used other appropriate analytical techniques (e.g., infrared spectroscopy and nuclear magnetic resonance spectroscopy) to compare GEGR and GEWR. Therefore, the agency concludes that data from these techniques, as well as the data from the gas chromatographic analyses, adequately demonstrate that GEGR and GEWR are chemically similar.

Because the agency has determined that GEGR and GEWR are similar with respect to the identity of their chemical components and that any difference in the ranges for the components of GEGR and GEWR are not significantly different and would be of no toxicological concern, there is no need for toxicological testing of GEGR to demonstrate that the petitioned use is safe.

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 3A4749 (68 FR 59794). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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 file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections (see **DATES**). 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.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from D. Doell, FDA, Division of Petition Review, Chemistry Review Group, and David Carlson, FDA, Division of Petition Review, Toxicology Review Group I, to A. Zajac, FDA Division of Petition Review, Regulatory Review Group I, February 17, 2005.

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 172.735 is amended by revising the section heading and the introductory text to read as follows:

§ 172.735 Glycerol ester of wood or gum rosin.

Glycerol ester of wood or gum rosin may be safely used in food in accordance with the following prescribed conditions:

* * * * *

Dated: March 18, 2005.

Leslye M. Fraser,

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

[FR Doc. 05–6089 Filed 3–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Zeranol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being removed from the animal drug regulations.

DATES: This rule is effective March 29, 2005.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 38–233 for RALGRO (zeranol), a subcutaneous implant used in cattle and in sheep for improved feed efficiency and/or increased rate of weight gain. The supplemental NADA provides for the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being removed from part 556 (21 CFR part 556). The supplemental application is approved as of March 4, 2005, and the regulations are amended in § 556.760 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows: