PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 Amended

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

Paragraph 6004 Class E4 Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ASO FL E4 Cocoa Beach Patrick AFB, FL [NEW]

Cocoa Beach, Patrick Air Force Base, FL
(Lat. 28°14′06″ N, long. 80°36′36″ W)

That airspace extending upward from the surface within 3.4 miles each side of the Patrick TACAN 034° radial, extending from the 5.3-mile radius to 7.3 miles northeast of the airport. This Class E airspace is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

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Issued in College Park, Georgia, on March 11, 2005.

Mark D. Ward,

Acting Area Director, Air Traffic Division, Southern Region.

[FR Doc. 05–6069 Filed 3–28–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

[Docket No. 2005N–0077]

Color Additive Certification; Increase in Fees for Certification Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to amend the color additive regulations by increasing the fees for certification services. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act (the act). The fees are intended to recover the full costs of operation of FDA's color certification program.

DATES: The interim final rule is effective April 28, 2005. Submit written or electronic comments by May 31, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0077 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. 2005N–0077 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 No(s). or Regulatory Information Number (RIN) for this rulemaking. All comments 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 comments and additional information on the rulemaking process, see the ''Opportunity for Public Comment'' 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(s), 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: Robert MacLeod, Division of Budget Execution (HFA–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–887–3923; and Theodor J. Dougherty, Division of Accounting (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5032.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is increasing the fees provided for in the agency's regulations for certifying color additives. This modification is necessary because of a general increase in all costs of operating the certification program.

The fee schedule for color additive certification is designed to cover all the costs involved in certifying batches of color additives. This includes both the cost of specific tests required by the regulations and the general costs associated with the certification program, such as costs of accounting, reviewing data, issuing certificates, and conducting research and establishment inspections.

Section 721(e) of the act (21 U.S.C. 379(e)) requires that fees necessary to provide, maintain, and equip an adequate color additive certification program be specified in agency regulations. The current fee schedule specified in the regulations became effective in 1994. Since 1994, the costs of the certification program significantly increased as a result of escalating staff payroll, rent and facility charges, as well as general operational expenses including equipment.

As is evidenced by the increased costs incurred since 1994, the current fee schedule is insufficient to provide, equip, and maintain an adequate certification service. Therefore, an immediate increase is necessary. All cost estimates are described in the ''2003 Color Certification Fee Study.'' A copy of this document is on file at the Division of Dockets Management (see **ADDRESSES**).

II. Effective Date

The agency is issuing this amendment as an interim final rule effective (see **DATES**). The establishment of fees necessary to provide, equip, and maintain an adequate certification service for colors has been mandated by Congress under section 721(e) of the act. As certification services are provided to industry directly by FDA, the setting of a fee schedule to pay for these services is a matter particularly within the purview and expertise of the agency. The fees established by this regulation have been based on cost accounting methods using data compiled by the agency. Increasing the fees by $0.05 per pound will ensure the viability of the certification program and offset the increased costs of maintaining this program. The fee for straight colors including lakes will be $0.35 per pound (a $0.05 per pound increase) with a minimum fee of $224. There are similar increases in fees for repacks of certified

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*.