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George J. Weise,

Commissioner of Customs.

Approved: December 22, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–1991 Filed 1–31–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

[Docket No. 94C–0041]

Color Additive Certification; Increase in Fees For Certification Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 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, including the unfunded liability of the Civil Service Retirement Fund and the appropriate overhead costs of the Public Health Service (PHS) and the Department of Health and Human Services (DHHS).

DATES: Effective March 4, 1996.

FOR FURTHER INFORMATION CONTACT: David R. Petak, Accounting Branch (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1766.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 29, 1994 (59 FR 60898), FDA issued an interim rule to amend the color additive regulations by increasing the fee for certification services. The change in fees was necessary so that FDA could recover the full costs of operation of its color certification program, including the unfunded liability of the Civil Service Retirement Fund and the appropriate overhead costs of PHS and DHHS. The fee schedule in effect before publication of the interim rule had been in place since 1982. While costs of the certification program have increased through the years, until 1991, the steady growth of the color additive market and corresponding increase in the batches certified generated sufficient revenue to cover these increased costs. The fee schedule is designed to cover the costs involved in the certifying of batches of color additive. These costs include 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.

Since 1991, however, the volume of batches certified has leveled off, while the costs have continued to rise at approximately 10 percent per year. Moreover, the old fee schedule did not reflect all applicable overhead costs for the program. It did not reflect the costs of management support provided by both PHS and DHHS, personnel costs for the unfunded liability portion of the Civil Service Retirement Fund, and ancillary costs of space, equipment, travel, and supplies. The agency announced in the November 1994 notice that it concluded that it is necessary to include these costs in the calculation of the fees to ensure that the fees fully cover the costs of certification. Because section 721(e) of the act (21 U.S.C. 379e(e)) requires payment of such fees necessary to provide, maintain, and equip an adequate certification service, an immediate increase was necessary.

The fee for straight colors including lakes is $.30 per pound (a $.05 per pound increase) with a minimum fee of $192. There are similar increases in fees for repacks of certified color additives and color additive mixtures. In addition, the interim rule announced the agency's tentative conclusion that fees would increase at a rate that is proportional to Federal salary increases, commencing with pay raises on or after January 1, 1996. This provision would permit FDA to set initial fees lower than they would otherwise be set. Interested persons were given until February 13, 1995, to comment on the interim rule. One letter was received in response to the interim rule from the International Association of Color Manufacturers (IACM). A description of the comment and the agency's response is as follows.

II. Comment

IACM, a trade association representing firms that manufacture certified color additives for use in foods, drugs, cosmetics, and medical devices, objected to the fee escalation provision, supported refunds of surplus fees, and suggested alternatives to the certification program.

In support of its objection to the escalator provision, IACM stated that it was opposed to an automatic annual increase in the color certification fees because it was contrary to section 721(e) of the act. IACM argued that Congress clearly intended that such fee increases would have to be specified in a proposed regulation with an opportunity for public notice and comments. IACM further stated that the fee study that FDA made available does not support the need for automatic fee increases and requested clarification of all the factors (e.g., local pay rate increase) that FDA intended to use as a basis for the automatic fee increase. IACM also requested more time to comment on these factors. In addition, IACM supported refunds of surplus fees but requested that FDA include a statement that it is ''* * * committed to making refunds.'' Lastly, IACM suggested that, in light of FDA's decision to increase the fee and provide for an automatic fee escalator, FDA should consider alternative methods of certification such as certifying private laboratories or certifying an individual company to conduct its own certification.

After due consideration FDA finds that it is persuaded by IACM's comments in support of its objection to the escalator provision, and the agency will not implement this provision. The agency will continue with its past policy of monitoring color certification costs and set fees as required by section 721(e) of the act as necessary to provide, maintain, and equip an adequate certification service. FDA will continue to closely monitor the certification fee structure and will continue with its policy of refunding any excess of funds in proportion to workload of each company that sought color certification. Accordingly, FDA is removing § 80.10(c) (21 CFR 80.10(c)) from the regulations.

IACM's request that FDA consider alternatives to the certification program are outside the scope of interim rule, and since the agency is returning to the past procedure for determining color additive certification fees, the issue needs no further consideration at this time. Thus, FDA is not making any additional modifications to § 80.10. The interim rule adopted on November 29, 1994, is therefore permanent, with the only modification that § 80.10(c) is withdrawn, and § 80.10(d) is redesignated as § 80.10(c) to replace it.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 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 $450,000 per year and would be distributed among approximately 30 companies who would pay an increased fee that is proportional to the number of pounds of color that they certify. Because the great majority of these costs will be borne by a few firms that have a dominant share of the market, the agency certifies that the 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.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24 (a)(8) 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.

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 Foods and Drugs, the interim rule published in the Federal Register of November 29, 1994 (59 FR 60898) is confirmed with the following changes to 21 CFR part 80:

PART 80—COLOR ADDITIVE CERTIFICATION

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

Authority: Secs. 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371, 379e).

§ 80.10 [Amended]

2. Section 80.10 *Fees for certification services* is amended by removing paragraph (c) and by redesignating paragraphs (d), (e), and (f) as paragraphs (c), (d), and (e), respectively.

Dated: January 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1977 Filed 1–31–96; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FL–064–1–7179a; FRL–5305–7]

Approval and Promulgation of Implementation Plans: Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to Florida's State Implementation Plan (SIP) to allow the State of Florida to issue Federally enforceable state operating permits (FESOP). On December 21, 1994, the State of Florida through the Florida Department of Environmental Protection (FDEP), submitted a SIP revision fulfilling the requirements necessary for a state FESOP program to become Federally enforceable. In order to extend the Federal enforceability of Florida's FESOP program to hazardous air pollutants (HAP), EPA is also approving Florida's FESOP program pursuant to section 112 of the Clean Air Act as amended in 1990 (CAA) so that Florida may issue Federally enforceable state operating permits for HAP.

DATES: This final rule is effective April 1, 1996 unless adverse or critical comments are received by March 4, 1996. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Written comments should be addressed to Gracy R. Danois, at the EPA Regional Office listed below. Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE, Atlanta, Georgia 30365.

Florida Department of Environmental Protection, Twin Towers Office Building, 2600 Blair Stone Road, Tallahassee, Florida 32399–2400.

FOR FURTHER INFORMATION CONTACT: Gracy R. Danois, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347–3555, extension 4150. Reference file FL–064–1–7179a.

SUPPLEMENTARY INFORMATION:

I. Summary of State Submittal

On December 21, 1994, the State of Florida through the FDEP submitted a SIP revision designed to make certain permits issued under the State's existing minor source operating permit program Federally enforceable pursuant to EPA requirements as specified in a Federal Register notice, ''Requirements for the preparation, adoption, and submittal of implementation plans; air quality, new source review; final rules.'' (see 54 FR 22274, June 28, 1989). Additional materials were provided by FDEP to EPA in a supplemental submittal on April 24, 1995.

Florida will continue to issue permits which are not Federally enforceable under its existing minor source operating permit rules as it has done in the past. The SIP revision, which is the subject of this document, adds requirements to Florida's current minor source operating permit program, which allows the State to issue FESOP. This voluntary SIP revision allows EPA and citizens under the CAA to enforce terms and conditions of Florida's FESOP program. Operating permits that are issued under the State's FESOP program that is approved into the SIP and under section 112(l), will provide Federally enforceable limits to an air pollution source's potential to emit. Limiting a source's potential to emit through Federally enforceable operating permits can affect the applicability of Federal regulations, such as title V operating permits, New Source Review (NSR) preconstruction permits, Prevention of Significant Deterioration (PSD) preconstruction permits for criteria pollutants and federal air toxics requirements mandated under section 112 of the CAA, to a source.

In the aforementioned June 28, 1989, Federal Register document, EPA listed