

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Part 80

DMB

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Comments:	None

[Docket No. 2005N-0077]

Color Additive Certification; Increase in Fees for Certification Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; technical amendment; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is amending an interim final rule (IFR) that was published in the **Federal Register** of March 29, 2005 (70 FR 15755). The IFR amended the color additive regulations by increasing the fees for certification services. The IFR was published with one typographical error regarding fees for repacks of certified color additives and color additive mixtures. FDA also inadvertently omitted the color certification fee study referenced in the IFR from the docket at the time of publication. This document corrects the typographical error in the fees for repacks of certified color additives and color additive mixtures, announces the availability of the referenced color certification fee study, and provides for additional time to submit comments.

DATES: This amendment is effective [*insert date 30 days after date of publication in the **Federal Register***]. Submit written or electronic comments by [*insert date 60 days after date of publication in the **Federal Register***].

ADDRESSES: You may submit comments, identified by Docket No. 2005N-0077, by any of the following methods:

Electronic Submissions

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Submit electronic comments in the following ways:

- 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.

Written Submissions

Submit written submissions in the following ways:

- 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the “Comments” 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: Kathleen Klausing, Division of Budget Execution (HFA-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7021; 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

In the **Federal Register** of March 29, 2005 (70 FR 15755), FDA issued an IFR to amend the color additive regulations by increasing the fees for certification services in 21 CFR 80.10. The change in fees was necessary so that FDA could continue to provide, maintain, and equip an adequate color certification program as required by section 721(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379(e)). The fees are intended to recover the full costs of operation of FDA's color certification program. The IFR went into effect on April 28, 2005. FDA requested written or electronic comments by May 31, 2005.

FDA subsequently discovered: (1) That the referenced 2003 color certification fee study had inadvertently been omitted from the docket and (2) that there was a typographical error regarding the fees for repacks of certified color additives and color additive mixtures in the codified portion of the IFR.

II. 2003 Color Certification Fee Study

The agency has made available the color certification fee study that describes the cost estimates reflected in the March 29, 2005, IFR. FDA stated in the IFR that the document entitled "2003 Color Certification Fee Study"

is on file at the Division of Dockets Management. FDA subsequently discovered that we had inadvertently omitted the document from the docket at the time of publication. The agency made the document available at the Division of Dockets Management (see **ADDRESSES**) on May 16, 2005.

III. Fee Listing Typographical Error

The agency is also amending the March 29, 2005, IFR (70 FR 15755 at 15756) regarding fees for repacks of certified color additives and color additive mixtures. Before issuance of the IFR, § 80.10(b) provided, in relevant part, “*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 * * * shall be: * * * (2) Over 100 pounds but not over 1,000 pounds—\$30 plus six cents for each pound over 100 pounds*” (emphasis added). In revising that portion of the codified, we intended to increase the fees for repacks of certified color additives and color additive mixtures for the first 100 pounds, i.e., from \$30 to \$35, but maintain the fee of 6 cents for each pound over 100 pounds. However, we inadvertently specified “\$0.05” rather than specifying “\$0.06.” This provision should read, in relevant part, “(2) Over 100 pounds but not over 1,000 pounds—\$35 plus \$0.06 for each pound over 100 pounds.” FDA is correcting this typographical error in the codified language by way of this technical amendment.

IV. Analysis of Impacts

FDA has examined the impacts of the March 29, 2005, IFR 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) (70 FR 15755 at 15756). Based on this analysis of the impact of the IFR, the technical amendment to the IFR described in section III would generate a cost of \$0

to \$2,000 per year. Therefore, this technical amendment is not a significant regulatory action as defined by the Executive Order.

The technical amendment does not necessitate a change in our certification, under the Regulatory Flexibility Act. The IFR, as amended, will not have a significant economic impact on a substantial number of small entities. In addition, the IFR, as amended, does not change our expectation that this rule will not result in any 1-year expenditure that would meet or exceed the threshold amount triggering a written statement under the Unfunded Mandates Reform Act.

V. Environmental Impact

The agency has determined under 21 CFR 25.22(a) that, as amended in this document, the March 29, 2005, IFR 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.

VI. Opportunity for Public Comment

Under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e), FDA found in the March 29, 2005, IFR 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 (70 FR 15755 at 15756). FDA continues to find it necessary to implement the amended fee increase as soon as possible to preserve adequate funds for the program. The agency believes, however, that it is appropriate to invite and consider additional public comments on these requirements. Any comments already received by FDA on the March 29, 2005, IFR do not need to be resubmitted to the agency. The agency is considering them at this time and will address them at a later date.

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 comments 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 paragraph (b) (2) to read as follows:

§ 80.10 Fees for certification services.

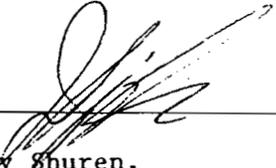
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(b) * * *

(2) Over 100 pounds but not over 1,000 pounds—\$35 plus \$0.06 for each pound over 100 pounds.

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Dated: 11/29/06
November 29, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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