marketing MEDIHALER ERGOTAMINE in November 1991.

G. Ipratropium Bromide

Oral pressurized MDIs that contain ipratropium bromide are listed in § 2.125(e)(4)(v) as an essential use. ATROVENT CFC MDI is the only oral pressurized MDI that has been marketed and contains ipratropium bromide with an ODS. Boehringer Ingelheim Pharmaceuticals, the manufacturer of ATROVENT CFC MDI, has informed us that they stopped marketing ATROVENT CFC MDIs in January 2006. This direct final rule does not affect MDIs containing ipratropium bromide and albuterol sulfate in combination, marketed as COMBIVENT, which are listed in § 2.125(e)(4)(viii) as a separate essential use.

H. Wholesale and Retail Stocks

Based on information given to us by the manufacturers, we have concluded that any beclomethasone, dexamethasone, fluticasone, bitolterol, salmeterol, and ergotamine tartrate ODS MDIs that may be in retail or wholesale stocks will have passed their expiration dates by the effective date for removal of § 2.125(e)(1)(i), (e)(1)(ii), (e)(1)(iv), (e)(2)(ii), (e)(4)(i), and (e)(4)(ii). Boehringer Ingelheim Pharmaceuticals, the manufacturer of ipratropium bromide, has informed us that any ipratropium bromide that may be in retail or wholesale stocks will have passed its expiration date by July 2007. Accordingly, we have set the effective date for removal of § 2.125(e)(4)(v) as August 1, 2007.

V. Environmental Impact

We have carefully considered, under 21 CFR part 25, the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. Our finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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 direct final rule is not a significant regulatory action as defined by 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. Because we are removing the essential use designations for certain drug products that are either no longer being marketed or are no longer being marketed in a formulation containing ODSs, the agency certifies that the direct final rule will not have a significant economic impact on a substantial number of small entities.

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 $118 million, using the most current (2004) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. The Paperwork Reduction Act of 1995

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

VIII. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, we do not plan to prepare a federalism summary impact statement for this rulemaking procedure. We invite comments on the federalism implications of this direct final rule.

IX. Request for Comments

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 copies of any written comments are to be submitted, 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 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, the Clean Air Act, and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, 21 CFR part 2 is amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

■ 1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

§ 2.125 [Amended]

■ 2. Section 2.125 is amended by removing and reserving paragraphs (e)(1)(i), (e)(1)(ii), (e)(1)(iv), (e)(2)(ii), (e)(4)(i), (e)(4)(ii), and (e)(4)(v).

Dated: October 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20797 Filed 12–6–06; 8:45 am]

BILLING CODE 4160–01–S

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; 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 January 8, 2007. Submit written or electronic comments by February 5, 2007.

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

Electronic Submissions

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.

* * * * *

(b) * * *

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

* * * * *

Dated: November 29, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20800 Filed 12–6–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9296]

RIN 1545–BD60

Credit for Increasing Research Activities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final regulations (TD 9296) that were published in the **Federal Register** on Thursday, November 9, 2006 (71 FR 65722) relating to the computation and allocation of the credit for increasing research activities for members of a controlled group of corporations or a group of trades or businesses under common control.

DATES: This correction is effective November 9, 2006.

FOR FURTHER INFORMATION CONTACT: Nicole R. Cimino (202) 622–3120 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under section 41 of the Internal Revenue Code.

Need for Correction

As published, final regulations (TD 9296) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.41–6 is amended by revising paragraph (j)(2), last sentence to read as follows:

§ 1.41–6 Aggregation of expenditures.

(j) * * *

(2) * * * For taxable years ending on or after May 24, 2005, and before November 9, 2006, see § 1.41–6T(d) as contained in 26 CFR part 1, revised April 1, 2006.

■ **Par. 3.** Section 1.41–8 is amended by revising paragraph (b)(5), last sentence to read as follows:

§ 1.41–8 Special rules for taxable years ending on or after November 9, 2006.

(b) * * *

(5) * * * For taxable years ending on or after May 24, 2005, and before November 9, 2006, see § 1.41–8T(b)(5) as contained in 26 CFR part 1, revised April 1, 2006.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E6–20732 Filed 12–6–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9273]

RIN 1545–AX65

Stock Transfer Rules: Carryover of Earnings and Taxes; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains correction to final regulations (TD 9273) that were published in the **Federal Register** on Tuesday, August 8, 2006 (71 FR 44887) addressing the carryover of certain tax attributes, such as earnings and profits and foreign income tax accounts, when two corporations combine in a corporate reorganization or liquidation that is described in both section 367(b) and section 381 of the Internal Revenue Code.

DATES: The correction is effective August 8, 2006.