

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 71, 73, 74, 170, 171, 172, 180, and 184

[Docket No. 2006N-0391]

**Food and Color Additives and Generally Recognized As Safe Substances;
Technical Amendments**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations that address food and color additives and generally recognized as safe (GRAS) substances. The purpose of the amendments is to update the name of an FDA office, to correct minor errors in the Code of Federal Regulations (CFR), and to delete obsolete information. The technical amendments made by this final rule are editorial in nature and are intended to provide accuracy and clarity to the agency's regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1256.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations for parts 71, 73, 74, 170, 171, 172, 180 and 184 (21 CFR parts 71, 73, 74, 170, 171, 172, 180 and 184). Specifically, as a result of an FDA reorganization, the Office of Premarket Approval was renamed the Office of Food Additive Safety. Therefore, this rule updates the name and contact information for this office

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2006N-0391

NFR 1

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in §§ 71.1 and 171.1. In addition, FDA discovered that minor errors were inadvertently published in the CFR affecting its regulations that address food and color additives (parts 71, 73, 74, 170, 171, 172, and 180) and GRAS substances (part 184). This document makes the needed corrections.

The 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. The changes addressed in this document are as follows:

1. In §§ 71.1 *Petitions* and 171.1 *Petitions* the agency is updating contact information. In § 71.1 *Petitions*, the regulations currently identify the Office of Premarket Approval as the FDA office responsible for receiving petitions. The new name for the Office of Premarket Approval is the Office of Food Additive Safety. In § 171.1 *Petitions*, the regulations currently identify the Petitions Control Branch, Food and Drug Administration, Department of Health and Human Services, Washington, DC 20204 as the FDA office responsible for receiving petitions. The correct name and contact information is the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

2. Section 73.1128 *Mica-based pearlescent pigments* is redesignated as § 73.1350.

3. In § 73.2396 *Lead acetate*, the regulatory section citation for the labeling requirements for color additives (other than hair dye) is currently erroneously written as § 170.25 and is corrected to read § 70.25.

4. In § 74.2052 *D&C Black No. 2*, the agency is correcting a typographical error in the spelling of the chemical nomenclature. “Benzo[e]pyrene” is being corrected to read “Benzo[a]pyrene.”

5. In §§ 170.45 *Fluorine-containing compounds* and 184.1769a *Sodium metasilicate*, the agency is updating references to a regulatory section citation which has been recodified. Section 103.35 has been recodified as § 165.110. Accordingly, in § 170.45, reference to “§ 103.35(d)” is corrected to read “§ 165.110(d)” and in § 184.1769a, reference to “§ 103.35” is corrected to read “§ 165.110”.

6. The agency is also updating § 170.45 *Fluorine-containing compounds* to correct a reference to a section of the agency’s regulations which has been removed from the CFR. In § 170.45 the reference to “§ 250.203” is removed.

7. In § 172.510 *Natural flavoring substances and natural substances used in conjunction with flavors*, the agency is correcting a typographical error. The incorrect nomenclature “concretes” is being corrected to read “concentrates”.

8. In § 180.37 *Saccharin, ammonium saccharin, calcium saccharin and sodium saccharin*, the agency is correcting references to a regulatory section citation which has been removed from the CFR. In § 180.37, reference to “§ 100.130” is removed.

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are merely correcting nonsubstantive errors. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects

21 CFR Part 71

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 74

Color additives, Cosmetics, Drugs.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 180

Food additives.

21 CFR Part 184

Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 71, 73, 74, 170, 171, 172, 180, and 184 are amended as follows:

PART 71—COLOR ADDITIVE PETITIONS

- 1. The authority citation for 21 CFR part 71 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

§ 71.1 [Amended]

- 2. Section 71.1 is amended in paragraph (c) by removing “Office of Premarket Approval (HFS–200),” and by adding in its place “Office of Food Additive Safety (HFS–200),”.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

- 3. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.1128 [Redesignated]

- 4. Section 73.1128 is redesignated as § 73.1350.

§ 73.2396 [Amended]

- 5. Section 73.2396 is amended in paragraph (d)(1) by removing “170.25” and by adding in its place “§ 70.25”.

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

- 6. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 74.2052 [Amended]

- 7. Section 74.2052 is amended in paragraph (b)(9) by removing “Benzo[e]pyrene” and by adding in its place “Benzo[a]pyrene”.

PART 170—FOOD ADDITIVES

- 8. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

§ 170.45 [Amended]

- 9. Section 170.45 is amended by removing the phrase “as stated in § 250.203 of this chapter” and by removing “§ 103.35(d)” and adding in its place “§ 165.110(d)”.

PART 171—FOOD ADDITIVE PETITIONS

- 10. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 171.1 [Amended]

- 11. Section 171.1 is amended in paragraph (c) by removing

“Petitions Control Branch

Food and Drug Administration

Department of Health and Human Services

Washington, DC 20204.”

and by adding in its place

“Office of Food Additive Safety (HFS-200),

Center for Food Safety and Applied Nutrition,

Food and Drug Administration,

5100 Paint Branch Pkwy.,

College Park, MD 20740.”

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

- 12. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.510 [Amended]

- 13. Section 172.510 is amended in paragraph (b) by removing “concretes” and adding in its place “concentrates”.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

- 14. The authority citation for 21 CFR part 180 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

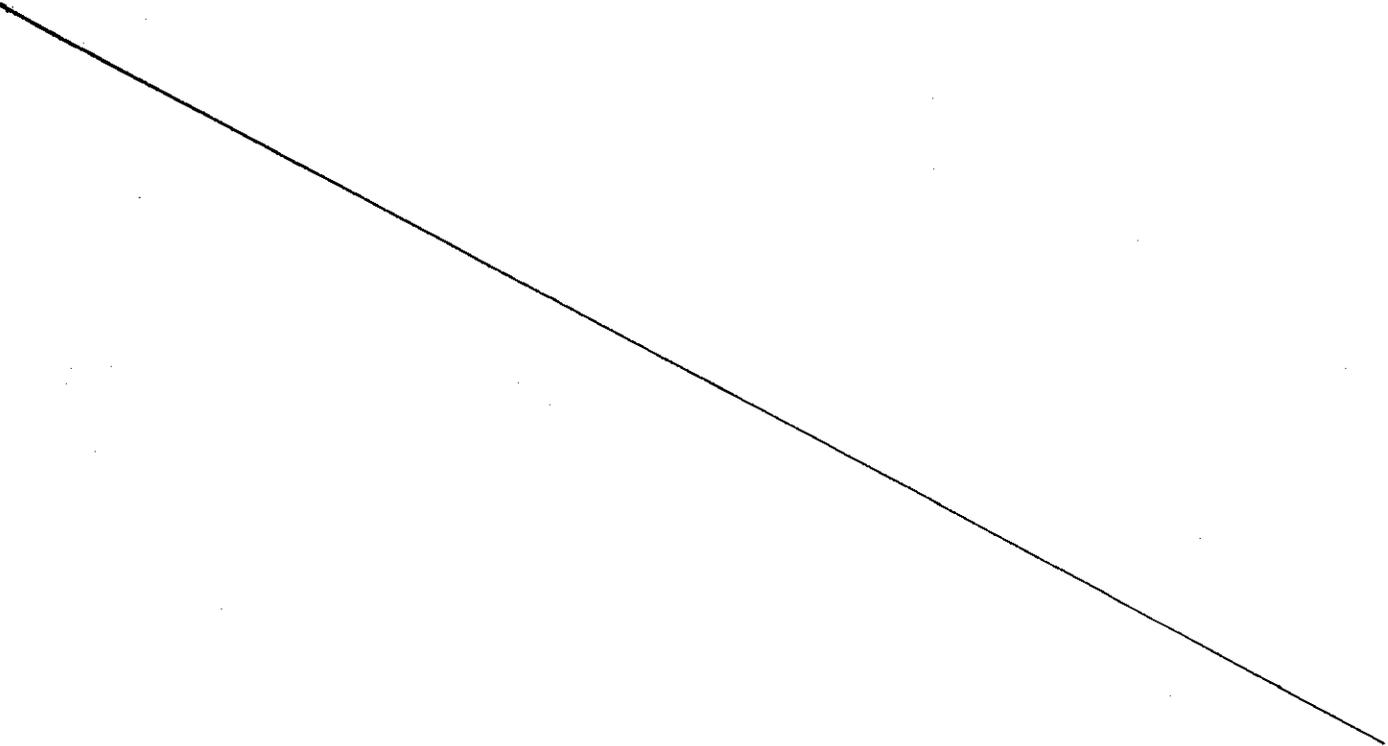
§ 180.37 [Amended]

- 15. Section 180.37 is amended in paragraph (f)(2)(iii) by removing “or § 100.130”.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

- 16. The authority citation for 21 CFR part 184 continues to read as follows:

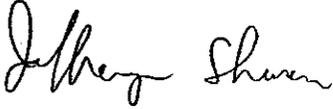
Authority: 21 U.S.C. 321, 342, 348, 371.



§ 184.1769a [Amended]

■ 17. Section 184.1769a is amended in paragraph (c)(2) by removing “§ 103.35” and adding in its place “§ 165.110”.

Dated: 2/28/07
February 28, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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