enters into the intitial open-end credit agreement. As provided in the commentary to § 226.17(b), closed-end credit disclosures may be delayed under these circumstances until the conversion of the open-end account to a closed-end transaction. In accounts secured by the consumer's principal dwelling, no new right of rescission arises at the time of conversion. Rescission rights under § 226.15 are unaffected.

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Section 226.24—Advertising

* * * * *

24(b) Advertisement of Rate of Finance Charge

1. *Annual percentage rate.* Advertised rates must be stated in terms of an "annual percentage rate," as defined in § 226.22. Even though state or local law permits the use of add-on, discount, time-price differential, or other methods of stating rates, advertisements must state them as annual percentage rates. Unlike the transactional disclosure of an annual percentage rate under § 226.18(e), the advertised annual percentage rate need not include a descriptive explanation of the term and may be expressed using the abbreviation "APR." The advertisement must state that the rate is subject to increase after consummation if that is the case, but the advertisement need not describe the rate increase, its limits, or how it would affect the payment schedule. As under § 226.18(f), relating to disclosure of a variable rate, the rate increase disclosure requirement in this provision does not apply to any rate increase due to delinquency (including late payment), default, acceleration, assumption, or transfer of collateral.

* * * * *

24(c) Advertisement of Terms That Require Additional Disclosure

* * * * *

Paragraph 24(c)(2)

* * * * *

3. *Annual percentage rate.* The advertised annual percentage rate may be expressed using the abbreviation "APR." The advertisement must also state, if applicable, that the annual percentage rate is subject to increase after consummation.

* * * * *

Board of Governors of the Federal Reserve System, March 31, 1986.

William W. Wiles

Secretary of the Board

[FR Doc. 86-6848 Filed 4-2-86; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 85-ASO-30]

Alteration of Transition Area, Hattiesburg, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment alters the description of the Hattiesburg, Mississippi, transition area to reflect a recent change in the name of the airport and decommissioning of the Hub City radio beacon. The present description of the transition area also contains language that provides for the unnecessary dual designation of airspace and has erroneous geographical coordinates for two existing airports. This action will correct these deficiencies and simplify the transition area description. No significant change in airspace designation will result from this proposed action.

EFFECTIVE DATE: 0901 UTC, May 8, 1986.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Supervisor, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

History

On Monday, January 13, 1986, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by altering the description of the Hattiesburg, Mississippi, transition area to reflect a change in airport name, revise geographical coordinates, and delete reference to a radio beacon which has been decommissioned. In addition, the description would be simplified to preclude the existing dual designation of airspace (50 FR 1385). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. This amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in FAA Order 7400.6B dated January 2, 1986.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations alters the Hattiesburg, Mississippi, transition area to reflect the proper name of the associated airport, correcting the coordinates of the airport and deleting reference to a decommissioned radio beacon.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Transition area.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); [14 CFR 11.69]; 49 CFR 1.47.

§ 71.181 [Amended]

2. By amending § 71.181 as follows:

Hattiesburg, MS—[Revised]

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Bobby L. Chain Municipal Airport (lat. 31°15'54" N., long. 89°15'11" W.); within an 8.5-mile radius of Pine Belt Regional Airport (lat. 31°28'01" N., long. 89°20'13" W.); within 3 miles each side of the Eaton VORTAC 181° radial, extending from the 8.5-mile radius area to 8.5 miles south of the VORTAC.

Issued in East Point, Georgia, on March 3, 1986.

James L. Wright,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 86-7323 Filed 4-2-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 85-ASO-28]

Alteration of Transition Area, Lawrenceburg, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment alters the Lawrenceburg, Tennessee, transition area by revising the coordinates of the airport and reducing the size of the associated transition area arrival

extension. The coordinates of the airport are inaccurate and this action will correct the error. The Lawrenceburg radio beacon, which was previously located 1.4 miles north of the airport, has been relocated to an on-airport site. This relocation required a change in the instrument approach procedure which, in turn, permits a reduction in the size of the transition area arrival extension. Thus, the floor of controlled airspace north and northwest of the airport, may be raised from 700 to 1,200 feet above the surface.

EFFECTIVE DATE: 0901 UTC, May 8, 1986.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Supervisor, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763–7646.

SUPPLEMENTARY INFORMATION:

History

On Friday, December 27, 1985, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) correcting the geographical coordinates of Lawrenceburg Municipal Airport and raising the floor of controlled airspace north and northwest of the airport from 700 to 1,200 feet above the surface (50 FR 52932). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. This amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in FAA Order 7400.6B dated January 2, 1986.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations corrects the coordinates of the Lawrenceburg Municipal Airport and raises the floor of controlled airspace north and northwest of the airport to 1,200 feet from 700 feet above the surface.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Transition area.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); [14 CFR 11.69]; 49 CFR 1.47.

2. By amending § 71.181 as follows:

Lawrenceburg, TN—[Revised]

That airspace extending upwards from 700 feet above the surface within a 7-mile radius of Lawrenceburg Municipal Airport (Lat. 35°14'07" N., Long. 87°15'30" W.); within 3 miles each side of the 005° bearing from Lawrenceburg RBN (Lat. 35°14'08" N., Long. 87°15'39" W), extending from the 7-mile radius area to 8.5 miles north of the RBN.

Issued in East Point, Georgia, on March 3, 1986.

James L. Wright,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 86–7324 Filed 4–2–86; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to hearings; imports and exports; certification following inspections; detention of meat, poultry, eggs, and related products, issuance of reports of minor violations; notification of defects in, and repair or replacement of, electronic products; detention of adulterated or misbranded medical devices; certification of true copies and use of department seal; and disclosure of official records. Titles of officials delegated the authorities above are being updated or deleted where appropriate because of reorganizations.

EFFECTIVE DATE: April 3, 1986.

FOR FURTHER INFORMATION CONTACT: Melissa M. Moncavage, Office of Management and Operations (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: Four reorganizations in FDA require FDA to update the list of delegates in several delegations of authority. This document retitles, adds, and deletes delegates from the lists in the delegation of authorities affected by the reorganizations, as appropriate. FDA realigned functions in the Immediate Office of the Commissioner which retitled the Executive Secretariat as the Office of the Executive Assistant and established two staffs titled the Executive Secretariat and the Program Management Staff (50 FR 36678; September 9, 1985). References to the Executive Secretariat are revised to include the following three titles: the Director, Office of the Executive Assistant; the Director, Executive Secretariat; and the Director, Program Management Staff. FDA retitled the Office of Legislation and Information as the Office of Legislative Affairs and established an Office of Public Affairs (50 FR 34759; August 27, 1985). For delegations pertaining to public affairs activities, references to the Office of Legislation and Information are changed to the Office of Public Affairs. FDA retitled the Minneapolis Center for Microbiological Investigations (January 15, 1986) as the Center for Microbiological Investigations and merged it into the Minneapolis District Office. References to the Minneapolis Center for Microbiological Investigations are deleted. In addition, FDA changed the Houston Station Office to a Resident Post (August 1, 1985). References to Chiefs of Station Offices are changed to Chief, St. Louis Station Office.

FDA is revising the following sections under Part 5 in accordance with the reorganizations: Under § 5.22 *Certification of true copies and use of Department seal* (21 CFR 5.22), Chiefs of Station Offices is changed to the Chief, St. Louis Station Office; the Director, Executive Secretariat is changed to the Director, Office of the Executive Assistant, the Director, Executive Secretariat, and the Director, Program

Management Staff; the Minneapolis Center for Microbiological Investigations is deleted; and Office of Legislation and Information is changed to Office of Public Affairs. Under § 5.23 *Disclosure of official records* (21 CFR 5.23), the Director, Executive Secretariat is changed to the Director, Office of the Executive Assistant, the Director, Executive Secretariat, and the Director, Program Management Staff; and Minneapolis Center for Microbiological Investigations is deleted. Under the following sections, Chiefs of Station Offices, is changed to the Chief, St. Louis Station Office: § 5.30 *Hearings* (21 CFR 5.30), § 5.36 *Certification following inspections* (21 CFR 5.36), § 5.37 *Issuance of reports of minor violations* (21 CFR 5.37), § 5.45 *Imports and exports* (21 CFR 5.45), § 5.47 *Detention of adulterated or misbranded medical devices* (21 CFR 5.47), § 5.63 *Detention of meat, poultry, eggs, and related products* (21 CFR 5.63), and § 5.89 *Notification of defects in, and repair or replacement of, electronic products* (21 CFR 5.89).

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR Part 5 continues to read as follows:

. **Authority:** Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)); 21 CFR 5.10.

2. In § 5.22 by removing paragraph (a)(12)(v), by redesignating paragraph (a)(12) (vi) and (vii) as paragraph (a)(12) (v) and (vi), and by revising paragraph (a) (2), (6), and (12) (iii) to read as follows:

§ 5.22 Certification of true copies and use of Department seal.

(a) * * *

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

* * * * *

(6) The Director, Freedom of Information Staff, Office of Public Affairs.

* * * * *

(12) * * *

(iii) The Chief, St. Louis Station Office.

* * * * *

3. In § 5.23 by removing paragraph (a)(8), by redesignating paragraph (a) (9) and (10) as paragraph (a) (8) and (9), and by revising paragraph (a)(2) to read as follows:

§ 5.23 Disclosure of official records.

(a) * * *

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

* * * * *

4. In § 5.30 by revising paragraphs (a)(7) and (c)(8) to read as follows:

§ 5.30 Hearings.

(a) * * *

(7) The Chief, St. Louis Station Office.

* * * * *

(c) * * *

(8) The Chief, St. Louis Station Office.

* * * * *

5. By revising § 5.36 to read as follows:

§ 5.36 Certification following inspections.

Regional Food and Drug Directors, District Directors, and the Chief, St. Louis Station Office, are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

6. In § 5.37 by revising paragraph (a)(5)(iv) and the introductory text of paragraph (b)(4) to read as follows:

§ 5.37 Issuance of reports of minor violations.

(a) * * *

(5) * * *

(iv) The Chief, St. Louis Station Office.

(b) * * *

(4) Regional Food and Drug Directors, District Directors, and the Chief, St. Louis Station Office, when such functions relate to:

* * * * *

7. In § 5.45 by revising the introductory texts of paragraphs (a) and (b) and by revising paragraphs (c)(5), (d), and (e)(4) to read as follows:

§ 5.45 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Chief, St. Louis Station Office, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), to perform the following functions or to designate officials to:

* * * * *

(b) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Chief, St. Louis Station Office, are authorized, under section 360 of the Public Health Service Act (PHSA), to perform the following functions or to designate officials to:

* * * * *

(c) * * *

(5) The Chief, St. Louis Station Office.

(d) The Regional Food and Drug Directors, District Directors, and the Chief, St. Louis Station Office, are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the PHSA that refers to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) * * *

(4) The Chief, St. Louis Station Office.

8. In § 5.47 by revising paragraph (d) to read as follows:

§ 5.47 Detention of adulterated or misbranded medical devices.

* * * * *

(d) The Chief, St. Louis Station Office.

9. By revising the introductory text of § 5.63 to read as follows:

§ 5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors, District Directors, and the Chief, St. Louis Station Office, are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

* * * * *

10. In § 5.89 by revising the introductory text of paragraph (a) to read as follows:

§ 5.89 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), are authorized to perform all functions of the

Commissioner of Food and Drugs relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 359 of the Public Health Service Act (the act) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Chief, St. Louis Station Office, are authorized to perform all such functions relating to:

* * * * *

Dated: March 24, 1986.

Adam J. Trujillo,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-7363 Filed 4-2-86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 5

Delegations of Authority and Organization; Revised Organization

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the regulations to set forth the organization structure of the agency and to update addresses for offices in several regions.

EFFECTIVE DATE: April 3, 1986.

FOR FURTHER INFORMATION CONTACT: Melissa M. Moncavage, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR Part 5 continues to read as follows:

Authority: Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)); 21 CFR 5.10.

2. By revising § 5.100 to read as follows:

§ 5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER

Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

Office of Regulatory Affairs.
Office of Management and Operations.
Office of Health Affairs.
Office of Science.
Office of Planning and Evaluation.
Office of Legislative Affairs.
Office of Public Affairs.
Office of Consumer Affairs.

CENTER FOR DRUGS AND BIOLOGICS

(Mailing address: 5600 Fishers Lane, Rockville, MD 20857)

Office of Management

Division of Planning and Evaluation.
Division of Administrative Management.
Division of Drug Information Resources.
Division of Information Systems Design.
Medical Library.

Office of Scientific Advisors and Consultants

Office of Consumer and Professional Affairs

Office of Compliance

Division of Drug Quality Evaluation.
Division of Drug Labeling Compliance.
Division of Manufacturing and Product Quality.
Division of Scientific Investigations.
Division of Regulatory Affairs.

Office of Drug Standards

Division of OTC Drug Evaluation.
Division of Biopharmaceutics.
Division of Generic Drugs.
Division of Drug Advertising and Labeling.
Division of Bioequivalence.

Office of Drug Research and Review

Division of Cardio-Renal Drug Products.
Division of Surgical-Dental Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology and Radiopharmaceutical Drug Products.
Division of Drug Biology.
Division of Drug Analysis.

Office of Biologics Research and Review

Division of Blood and Blood Products.
Division of Virology.
Division of Bacterial Products.
Division of Biochemistry and Biophysics.
Division of Product Quality Control.
Division of Anti-Infective Drug Products.
Division of Metabolism and Endocrine Drug Products.
Division of Product Certification.
Division of Biological Investigational New Drugs.

Office of Epidemiology and Biostatistics

Division of Epidemiology and Surveillance.
Division of Biometrics.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

(Mailing address: 200 C St. SW., Washington, DC 20204)

Office of Management

Division of Program Operations.
Division of Administrative Operations.
Division of Information Resources Management.

Office of Compliance

Division of Regulatory Guidance.
Division of Food and Color Additives.
Division of Cooperative Programs.

Office of Toxicological Sciences

Division of Toxicology.
Division of Pathology.
Division of Mathematics.

Office of Physical Sciences

Division of Chemical Technology.
Division of Color Technology.
Division of Cosmetics Technology.
Division of Chemistry and Physics.

Office of Nutrition and Food Sciences

Division of Consumer Studies.
Division of Nutrition.
Division of Food Technology.
Division of Microbiology.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

(Mailing address: 5600 Fishers Lane, Rockville, MD 20857)

Office of Management and Systems

Division of Resource Management.
Division of Information Services.
Division of Computer Services.
Division of Planning and Evaluation.

Office of Health Physics

Office of Health Affairs

Office of Standards and Regulations

Office of Compliance

Division of Radiological Products.
Division of Compliance Programs.
Division of Compliance Operations.
Division of Surveillance.

Office of Device Evaluation

Division of Cardiovascular Devices.
Division of Gastroenterology/Urology and General Use Devices.
Division of Anesthesiology, Neurology, and Radiology Devices.
Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices.
Division of Surgical and Rehabilitation Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic Devices.

Office of Science and Technology

Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences
Division of Biometric Sciences.
Division of Electronics and Computer Sciences.

Office of Training and Assistance

Division of Consumer Affairs.
Division of Small Manufacturers Assistance.
Division of Intergovernmental Programs.
Division of Technical Development.
Division of Professional Practices.
Division of Training Support.

CENTER FOR VETERINARY MEDICINE

(Mailing address: 5600 Fishers Lane, Rockville, MD 20857)

Office of Management.

Division of Administrative Management.

Office of New Animal Drug Evaluation

Division of Biometrics and Production Drugs.
Division of Drug Manufacturing and Controls.
Division of Therapeutic Drugs for Food Animals.
Division of Therapeutic Drugs for Non-Food Animals.

Office of Surveillance and Compliance

Division of Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Voluntary Compliance and Hearings Development.

Office of Science

Division of Veterinary Medical Research.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

(Mailing address: Jefferson, AR 72079)

Office of Management

Division of Management Services.
Division of Toxicological Data Management Systems.
Division of Facilities Engineering and Maintenance.

Office of Research

Division of Reproductive and Developmental Toxicology.
Division of Genetic Toxicology.
Division of Biochemical Toxicology.
Division of Comparative Toxicology.

Office of Research Services

Division of Chemistry.
Division of Microbiology.
Division of Animal Husbandry.

3. In § 5.115 by revising the entry for "Regions II, IV, V, VI, and IX" to read as follows:

§ 5.115 Field structure.

* * * * *

REGION II

Regional Field Office: 830 Third Ave., Brooklyn, NY 11232.
District Office: 850 Third Ave., Brooklyn, NY 11232.
District Office: 599 Delaware Ave., Buffalo, NY 14202.
District Office: 20 Evergreen Place, East Orange, NJ 07018.
District Office: Fernandez Juncos Ave., Stop 8½, Puerta de Tierra, San Juan, PR. Mail to: P.O. Box S–4427, San Juan, PR 00905.
Import District Office: 830 Third Ave., Brooklyn, NY 11232.

* * * * *

REGION IV

Regional Field Office: 60 Eighth St., Atlanta, GA 30309.
District Office: 60 Eighth St., Atlanta, GA 30309.
District Office: 297 Plus Park Blvd., Nashville, TN 37217.
District Office: 7200 Lake Ellenor Dr., Suite 120, Orlando, FL 32809.

REGION V

Regional Field Office: 1411 CNA Bldg., 55 East Jackson Blvd., Chicago, IL 60604.
District Office: Rm. 1222, 433 West Van Buren St., Chicago, IL 60607.
District Office: 1141 Central Parkway, Cincinnati, OH 45202–1097.
District Office: 1560 East Jefferson Ave., Detroit, MI 48207.
District Office: 240 Hennepin Ave., Minneapolis, MN 55401.

REGION VI

Regional Field Office: 3032 Bryan St., Dallas, TX 75204.
District Office: 3032 Bryan St., Dallas, TX 75204.
District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.

* * * * *

REGION IX

Regional Field Office: Rm. 568, Federal Office Bldg., 50 U.N. Plaza, San Francisco, CA 94102.
District Office: Rm. 506, Federal Office Bldg., 50 U.N. Plaza, San Francisco, CA 94102.
District Office: 1521 West Pico Blvd., Los Angeles, CA 90015–2486.

* * * * *

Dated: March 24, 1986.

Adam J. Trujillo,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–7362 Filed 4–2–86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 73

[Docket No. 84C–0192]

Listing of Color Additives for Coloring Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of 4-[2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one for coloring contact lenses. This action responds to a petition filed by Dow Corning Ophthalmics, Inc.

DATES: Effective May 6, 1986, except as to any provisions that may be stayed by the filing of proper objections; objections by May 5, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of June 27, 1984 (49 FR 26311), FDA announced that a color additive petition (CAP 4CO180) had been filed by Dow Corning Ophthalmics, Inc., P.O. Box 1767, Midland, MI 48640, proposing that the color additive regulations be amended to provide for the safe use of 4-[(2,4-dimethylphenyl)azo]-2-4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one for coloring silicone resin contact lenses. The petition was filed under section 706

of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 to the act (Pub. L. 94–295), Congress mandated the listing of color additives for uses in medical devices when the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of this material as a color additive in contact lenses is subject to regulation under the act. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive presently before the agency is subject to the statutory listing requirement.

III. Analysis of Data

To establish that the color additive 4-[(2,4-dimethylphenyl)-azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one is safe for use in coloring contact lenses, the petitioner submitted various toxicity data. In a primary ocular irritation study in rabbits, there was no ocular irritation from saline extracts of tinted lens material.

The petitioner also conducted in vitro cytotoxicity studies using HR218 human embryonic foreskin cells. No cytotoxic response was observed when 1 and 10 percent suspensions of the dye were tested, or when various extracts of the tinted lenses material were tested.

The agency calculated the upper limit of exposure to be 270 nanograms per day based on the following two factors. First, based on the information submitted by the petitioner, FDA estimated that the maximum use level of the color additive is 50 micrograms per lens. See, Memorandum of February 19, 1985, from Food Additive Chemistry Evaluation Branch to Petitions Control Branch, Re: Color Additives in Contact Lenses, which is on file in the Dockets Management Branch (address above) under the docket number appearing in the heading of this document and is available for public review between 9 a.m. and 4 p.m., Monday through Friday. Second, the agency made two worst-case assumptions: (1) That the user will replace lenses tinted with the color additive once each year with a new pair of lenses tinted with the color additive at a maximum use level; and (2) that 100 percent of the color additive migrates from these lenses into the eye over the 1-year period. Because these assumptions are a worst-case estimate, exposure to 4-[(2,4-dimethylphenyl)-azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one from its use for coloring contact lenses is likely to be far less than 270 nanograms per day.

Using the 10 percent concentration of the dye in the cytotoxicity studies for calculation purposes, FDA has determined that no cytotoxic effect was observed at approximately 125,000 times the concentration that would be in the eyes if 270 nanograms of the dye migrated into the eyes per day.

IV. Certification Considerations

Based on its review of relevant data, FDA concludes that the safety margin for use of this color additive is large enough to rule out any need for imposing a limitation on that amount of the color additive that may be present in the lens, beyond the limitation the only that amount necessary to accomplish the intended technical effect may be used. Also, based on its consideration of the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of the color additive listed in this final rule is not necessary for the protection of the public health.

V. Conclusions

Based on the data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of 4-[(2,4-dimethylphenyl)-azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one for coloring contact lenses. The agency further concludes on the basis of data submitted in the petition that this color additive is suitable for its intended use. Additionally, FDA concludes that because of the wide margin of safety it is not necessary to limit the color additive use to silicone resin contact lenses. Therefore, FDA is permitting use of this color additive with any suitable contact lens material and the agency is amending 21 CFR Part 73 of the color additive regulations by listing this color additive for use in contact lenses.

VI. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the use of the color additive in contact lenses are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Assessment

The agency has previously considered the environmental effects of this rule as announced in the Notice of Filing for CAP 4C0180 (June 27, 1984; 49 FR 26311). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 5, 1986 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority section for 21 CFR Part 73 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. Part 73 is amended in Subpart D by adding new § 73.3122 to read as follows:

§ 73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.

(a) *Identity.* The color additive is 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one (CAS Reg. No. 6407–78–9).

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: March 26, 1986.

M.D. Kinslow,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–7365 Filed 4–2–86; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 73

[Docket No. 85C–0378]

Phthalocyanine Green; Listing as a Color Additive for Coloring Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of phthalocyanine green for coloring contact lenses. This action responds to a petition filed by Optacryl, Inc.

DATES: Effective May 5, 1986, except as to any provisions that may be stayed by the filing of proper objections; objections by May 5, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Edward J. Machuga, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of September 25, 1985 (50 FR 38898), FDA announced that a color additive petition (CAP 3C0168) had been filed by Optacryl, Inc., 2890 South Tejon St., Englewood, CO 80110, proposing that 21 CFR Part 73 of the color additive regulations be amended to provide for the safe use of phthalocyanine green (Colour Index Pigment Green 7, C.I. No. 74260, CAS Reg. No. 1328–53–6) as a color additive in contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 to the act (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive comes in direct contract with the body for a significant period of time (21 U.S.C. 376(a)). The use of this material as a color additive in contact lenses is subject to regulation under the act. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive presently before the agency is subject to the statutory listing requirement.

III. Analysis of Data

To establish that the color additive phthalocyanine green is safe for use in contact lenses, the petitioner submitted various toxicity data. In a primary ocular irritation study in rabbits, there was no ocular irritation from saline extracts of the tinted lens material.

The petitioner also conducted cytotoxicity studies of the color additive using L–929 mouse fibroblast cells. When tested at a level of 0.5 percent, there were no adverse effects found in the study.

The agency also calculated the upper limit of exposure to be 270 nanograms per day based on the following two factors. First, based on the information submitted by the petitioner, FDA estimated that the maximum use level of the color additive is 50 micrograms per lens. See, Memorandum of February 19, 1985, from Food Additive Chemistry Evaluation Branch to Petitions Control Branch, Re: Color Additives in Contact Lenses, which is on file in the Dockets Management Branch (address above) under the docket number appearing in the heading of this document and is available for public review between 9 a.m. and 4 p.m., Monday through Friday. Second, the agency made two worst-case assumptions: (1) That the user will replace lenses tinted with the color additive once each year with a new pair of lenses tinted with the color additive at the maximum use level; and (2) that 100 percent of the color additive migrates from the lenses over the 1-year period. Because these assumptions are a worst-case estimate, exposure to this color additive from its use for coloring contact lenses is likely to be far less than 270 nanograms per day. In the case of this color additive, no cytotoxic effect was observed at approximately 62,000 times the concentration that would be in the eyes if 270 nanograms of the dye migrated into the eyes per day.

IV. Certification Considerations

Based on its review of relevant data, FDA concludes that the safety margin for use of this color additive is large enough to rule out any need for imposing a limitation on the amount of the color additive that may be present in the lens, beyond the limitation that only that amount necessary to accomplish the intended technical effect may be used. Also, based on its consideration of the factors listed in § 71.20(b) 21 CFR 71.20(b)), the agency concludes that certification of the color additive listed in this final rule is not necessary for the protection of the public health.

V. Conclusion

Based on the data in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of phthalocyanine green for coloring contact lenses. The agency further concludes, on the basis of data contained in the petition, that this color additive is suitable for its intended use. The agency, therefore, is amending 21 CFR Part 73 of the color additive