

all categories, unless already accomplished:

A. For airplanes with 30,000 or more cycles, accomplish the following within the next 100 additional cycles after the effective date of this AD:

1. Roll back or remove and retain insulation material from aft side of bulkhead web for approximately 15 inches outboard of RH/LH edge or ventral door cutout.

2. Clean as necessary and perform close detail visual check for cracks running along AD4 rivet rows, for attaching RH/LH horizontal stiffeners, P/N 9915558, at Z=14.00, 24.00, 34.00, 48.00 and 63.50. (Reference McDonnell Douglas Service Sketch SK 3110A, Figure 1, Sheet 6). Check for cracks for a distance of 15 inches outboard of RH/LH edge of ventral door cutout. Removal of existing finger doublers along edges of door cutout is not required. Primary areas of interest are the outboard edges of finger doublers.

3. In addition to above, on Group 1 aircraft identified in McDonnell Douglas DC-9 Alert Service Bulletin A53-144, perform a visual check for cracks in the web at the upper and lower ends of the fire support stiffeners. (Refer to McDonnell Douglas Service Sketch 3109.)

B. Rework any cracked bulkhead panels, per McDonnell Douglas Service Sketches SK 3525 (temporary), dated July 19, 1983, or SK 3524A (permanent), dated July 18, 1983.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes unpressurized to a base in order to comply with the requirements of this AD.

D. Alternate means of compliance which provide an equivalent level of safety may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-750 (54-60). These documents also may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California.

This Admendment becomes effective, January 9, 1984, and was effective earlier to those recipients of telegraphic AD T83-15-51, dated July 22, 1983.

(Sec. 313(a), 314(a), 601 through 610, and 1102 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 through 1430, and 1502); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89)

Note.—The FAA has determined that this regulation is an emergency regulation that is not major under section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an

emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption "FOR FURTHER INFORMATION CONTACT."

Issued in Seattle, Washington on December 21, 1983.

F. Isaac,

Acting Director, Northwest Mountain Region.

[FR Doc. 84-56 Filed 1-3-84; 8:45 am]

BILLING CODE 4910-13-M

#### 14 CFR Part 71

[Airspace Docket No. 83-AGL-11]

#### Alteration of Control Zone; Columbus, Ohio

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The nature of this Federal action is to alter the Port Columbus International Airport, Columbus, Ohio, control zone to revise/reduce the airspace currently designated for the control zone.

The intended effect of this action is to insure segregation of the aircraft using approach procedures in instrument weather conditions from other aircraft operating under visual weather conditions in controlled airspace.

EFFECTIVE DATE: March 15, 1983.

FOR FURTHER INFORMATION CONTACT: Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL-530, FAA, Great Lakes Region, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694-7360.

SUPPLEMENTARY INFORMATION: This action revises the Port Columbus International Airport control zone to accommodate existing airspace requirements. A review of designated airspace in the Columbus area prompted a rewrite to better and more accurately describe the airspace in the area. The revised description is presented in the text of this notice.

Aeronautical maps and charts will reflect the defined areas which will enable other aircraft to circumnavigate the area in order to comply with applicable visual flight rule requirements.

#### History

On the page 49863 of the Federal Register dated October 28, 1983, the

FAA proposed to amend § 71.171 of the Federal Aviation Regulations (14 CFR Part 71) so as to alter the Port Columbus International Airport, Columbus, Ohio, control zone. Interested parties were invited to participate in the rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Notice of Proposed Rulemaking.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.171 of Part 71 of the Federal Aviation Regulations was published in Advisory Circular AC 70-3A dated January 3, 1983.

#### List of Subjects in 14 CFR Part 71

Control zones/Aviation safety.

#### Adoption of the amendment

#### § 71.171 [Amended]

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 GMT, March 15, 1984, as follows:

#### Columbus, Port Columbus International Airport, OH

Within a 5-mile radius of Port Columbus International Airport (latitude 39°59'42" N., longitude 82°53'11" W.); within 1 mile each side of the 100° bearing from the center of the airport, extending from the 5-mile radius zone to 6 miles east of the airport; within 1 mile each side of the 280° bearing from the center of the airport, extending from the 5-mile radius zone to 6 miles west of the airport.

(Secs. 313(a), 314(a), 601 through 610, and 1102 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 through 1430, and 1502); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983))

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, it is certified that this—(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 will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Des Plaines, Illinois, on December 20, 1983.

Monte R. Belger,  
Acting Director,  
Great Lakes Region.

[FR Doc. 84-55 Filed 1-3-84; 8:45 am]  
BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. 83C-0179]

#### 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 in coloring contact lenses of the color polymeric reaction products formed by chemically bonding certain dyes, used singly or in combination, with poly(hydroxyethyl methacrylate). The reaction products are called "poly(hydroxyethyl methacrylate)-dye copolymers" in the listing regulation. The agency is taking this action in response to a petition filed by Ciba Vision Care.

**DATES:** Effective February 6, 1984; objections by February 3, 1984.

**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:** John L. Herrman, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of July 5, 1983 (48 FR 30758), FDA announced that a color additive petition (CAP 3C0174) has been filed by Ciba Vision Care, P.O. Box 105069, Atlanta, GA 30348, proposing "that the color additive regulations be amended to provide for the safe use of the following dyes chemically bonded to the lens polymer, singly or in various combinations, for coloring contact lenses: Reactive Blue 21 (CAS Reg. No. 73049-92-0), Reactive Black 5 (CAS Reg. No. 17095-24-8), Reactive Yellow 15 (CAS Reg. No. 60958-41-0), and Reactive Orange 78 (CAS Reg. No. 68189-39-9)." The petition was filed under section 706

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

The colored polymeric reaction products that are subject of this petition are formed when one or more of the dyes listed in § 73.3121(a) (21 CFR 73.3121(a)) are bonded with poly(hydroxyethyl methacrylate) on the front surface of a contact lens to form a thin layer of colored polymeric material on that surface. This polymeric material colors the contact lens.

Under the Medical Device Amendments of 1976 (Pub. L. 94-295), a color additive for use in a medical device must be listed when the color additive comes in direct contact with the body for a significant period of time (section 706(a) of the act). The polymeric reaction products of the reactive dyes and poly(hydroxyethyl methacrylate), called "poly(hydroxyethyl methacrylate)-dye copolymers" in § 73.3121, are color additives within the meaning of section 201(t) of the act (21 U.S.C. 321(t)) because they are substances made by a process of synthesis or similar artifice, and because they are capable of imparting color to food, drugs, cosmetics, or the human body if added or applied thereto. In the use considered here, the reactive dyes are merely starting materials and not color additives subject to section 706 of the act. In the reaction process that occurs in bonding the reactive dyes to the poly(hydroxyethyl methacrylate), the reactive dyes cease to exist as separate entities.

The use of the poly(hydroxyethyl methacrylate)-dye copolymers as color additives in contact lenses is subject to regulation under section 706(a) of the act. The lenses that have this colored polymeric material on their front surfaces are intended to be placed on the eye for several hours a day, each day, for 1 year or more. These color additives accordingly will come in direct contact with the body for a significant period of time. Consequently, the use of the color additives presented in the petition now before the agency is subject to the statutory listing requirement.

To establish that the color additives are safe for use in contact lenses, the petitioner submitted various toxicity data. In a primary ocular irritation study with extracts of lens material containing the color additives, and in a 21-day ocular irritation study with contact lenses tinted with the color additives, both of which were done in rabbits, neither the lens containing the color additives nor the extracts of the colored lens material caused ocular irritation under the conditions of these tests. The agency has also reviewed data

regarding the toxicity of potential impurities, such as unbound reactive dye starting materials, remaining in the lens. The reactive dye starting materials, being of lower molecular weight than the polymeric color additive, would be more readily absorbed into the body than the color additive and would thus be expected to show a greater toxic effect. FDA has concluded that, as a worst case, any material migrating from the color additive in the lens would not pose a greater safety concern than if the reactive dye starting materials were placed in the lens unbound, and all migrated into the eye over a 1-year period. This amount of migration would be equivalent to 5 to 45 micrograms of reactive dye starting material per lens or a total of 27 to 250 nanograms per day for both eyes, depending on the reactive dye used. The petitioner conducted cytotoxicity studies in which serial dilutions of the individual reactive dyes were applied directly to L-929 mouse fibroblast cells. For the reactive dye used in the greatest amounts, no toxic effect was seen at a concentration 1,300 times the concentration that would be in the eyes if 250 nanograms migrated into the eyes per day. All other reactive dyes showed no toxic effect with even greater factors above the worst case eye concentration, ranging up to 61,000 times the concentration that would be in the eyes from 27 nanograms per day.

On the basis of these studies, FDA concludes that the safety margin is sufficiently large that, for any foreseeable formulation, a limitation on the amount of these color additives that may be present on the lens, beyond the limitation that only that amount necessary to accomplish the intended technical effect may be used, is not required.

FDA received an anonymous comment in response to the notice of filing of this petition. The person making the comment claims that the dye-polymer reaction is reversible, resulting in the release of toxic dyes into the eye during the lifetime of the contact lens, but did not provide data to support that claim. Information in the petition shows that the dye-polymer reaction is reversible in alkali, but that the polymeric color additive is highly stable under the physiological conditions of the eye. The agency has also searched the toxicity literature and has found no data supporting the claim regarding the toxicity of the materials that would be released if the binding reaction were reversed. The agency therefore finds no basis for the assertions in the comment.

FDA, having reviewed the anonymous comment, data in the petition, and other

relevant material, concludes that there is a reasonable certainty that no harm will result from the proposed use of the reaction products of poly(hydroxyethyl methacrylate) with Reactive Black 5, Reactive Blue 21, Reactive Orange 78, and Reactive Yellow 15, used singly or in various combinations, for coloring contact lenses. To further assure the safety of the use of these color additives, FDA is establishing a requirement that the manufacturer wash the lens to remove unbound reactive dyes. The agency also concludes that the poly(hydroxyethyl methacrylate)-dye copolymers listed in § 73.3121 are suitable for their intended use. On the basis of factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of the color additive is not necessary for the protection of the public health.

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

The agency has previously concluded that this action will not have a significant impact on the human environment and that an environmental impact statement is not required. No new information or comments have been received that would alter the agency's previous determination that there is no significant impact on the human environment, and that an environmental impact statement is not required.

#### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

#### PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 73 is amended by adding new § 73.3121 under Subpart D, to read as follows:

#### § 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.

(a) *Identity.* The color additives are formed by reacting one or more reactive

dyes listed in this paragraph with poly(hydroxyethyl methacrylate), so that the sulfate group (or groups) of the dye is replaced by an ether linkage to the poly(hydroxyethyl methacrylate). The dyes are (1) Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt) (CAS Reg. No. 17095-24-8); (2) Reactive Blue 21 [copper, (29*H*,31*H*-phthalocyaninato(2-)-*N*(29),*N*(30),*N*(31),*N*(32))-, sulfo((4-((2-sulfooxy)ethyl)sulfonyl)phenyl)amino) sulfonyl derivs] (CAS Reg. No. 73049-92-0); (3) Reactive Orange 78 [2-naphthalene-sulfonic acid, 7-(acetyl-amino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-] CAS Reg. No. 68189-39-9]; and (4) Reactive Yellow 15 [benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-] (CAS Reg. No. 60958-41-0).

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

(2) As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive dyes.

(3) Authorization and compliance with 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 (the act). A person intending to introduce a device containing a poly(hydroxyethyl methacrylate)-dye copolymers listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with Subpart E of Part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(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.

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 3, 1984 file with the Dockets Management Branch (address above) written objection thereto. Objections shall show

how the person filing will be adversely affected by the regulation., specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in the 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.

*Effective date.* This regulation shall become effective February 6, 1984, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the *Federal Register*.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

Dated: December 28, 1983.

William F. Randolph,  
Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 84-31 Filed 1-3-84; 8:45 am]

BILLING CODE 4160-01-M

#### 21 CFR Part 452

[Docket No. 83N-0285]

#### Antibiotic Drug; Updating and Technical Changes; Correction

**AGENCY:** Food and Drug Administration.  
**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting the final rule that amended the antibiotic drug regulations by making corrections, updates, and minor technical changes. This document corrects the amendatory language to clarify the technical change that was made in § 452.510b(a)(1).

**EFFECTIVE DATE:** November 8, 1983.

**FOR FURTHER INFORMATION CONTACT:** Joan M. Eckert, National Center for Drugs and Biologics (HFN-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.