were received. Except for changes to V–228 that added the Chicago O'Hare, IL, and Northbrook, IL, intersection; V–420 that removed the portion of the airway from Chicago O'Hare to Badger, WI; V–170 which added a segment from Badger to Pullman, MI; and V–217 that added the portion of the airway from Chicago O'Hare to Badger, these amendments are the same as those proposed in the notice. Sections 71.123 and 75.100 of Parts 71 and 75 of the Federal Aviation Regulations were republished in Handbook 7400.6C dated January 2, 1987.

The Rule

These amendments to Parts 71 and 75 of the Federal Aviation Regulations alter the descriptions of ten Federal Airways, add one new airway and revoke Jet Route J–113. These changes are necessary because the planned commissioning of the Timmerman, WI, VORTAC has been canceled and the decommissioning of Badger, WI, VORTAC has been withdrawn. This action eliminates alternate airway descriptions in accordance with our ICAO agreement and realign other airways to improve traffic flows.

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. 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 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 Parts 71 and 75

Aviation safety, VOR Federal Airways and Jet Routes.

Adoption of the Amendments

Accordingly, pursuant to the authority delegated to me, Parts 71 and 75 of the Federal Aviation Regulations (14 CFR Parts 71 and 75) are amended, as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

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.

§ 71.123 [Amended]

2. Section 71.123 is amended as follows:

V–24 [Revised]

From Aberdeen, SD, via Watertown, SD; Redwood Falls, MN; Rochester, MN; Lone Rock, WI; INT Lone Rock 147° and Janesville, WI, 281° radials; Janesville; INT Janesville 112° and Northbrook, IL, 290° radials; to Northbrook.

V–398 [New]

From Aberdeen, SD, via INT Aberdeen 101° and Watertown, SD, 312° radials; Watertown; Redwood Falls, MN; Rochester, MN; Waukon, IA; to Lone Rock, WI.

V–30 [Amended]

By removing the words "Pullman, including a S alternate via INT Badger 121° and Pullman 282° radials;" and substituting the word "Pullman;"

V–82 [Amended]

By removing the words "Dells, WI; INT Dells 097° and Timmerman, WI, 322° radials; 6 miles wide; Timmerman" and substituting the words "to Dells, WI"

V–191 [Amended]

By removing the words "Northbrook, IL; INT Northbrook 332° and Badger, WI, 182° radials; Badger;" and substituting the words "Northbrook, IL; Badger, WI;"

V–217 [Amended]

By removing the words "From Chicago O'Hare, IL; INT Chicago O'Hare 019° and Badger, WI, 137° radials; INT Chicago Heights, IL, 358° and Milwaukee 121° radials; Badger;" and substituting the words "From INT Chicago O'Hare, IL, 316°/Joliet, IL, 360° and Northbrook, IL, 290° radials; INT Chicago O'Hare 316° and Badger, WI, 193° radials; Badger;"

V–228 [Amended]

By removing the words "Madison, WI, Janesville, WI; INT Janesville 112° and Northbrook, IL, 290° radials; Northbrook;" and substituting the words "Madison, WI; INT Madison 138° and Chicago O'Hare, IL, 316° radials; INT Chicago O'Hare 316° and Northbrook, IL, 290° radials; Northbrook;"

V–411 [Amended]

By removing the words "From Rochester, MN," and by substituting the words "From Lone Rock, WI, via Waukon, IA; Rochester, MN; INT"

V–127 [Revised]

From Bradford, IL; Polo, IL; to Rockford, IL.

V–170 [Amended]

By removing the words "Dells, WI; INT Dells 097° and Badger, WI, 307° radials; Badger; INT Badger 102° and Pullman, MI, 303° radials; Pullman;" and substituting the words "Dells, WI; INT Dells 097° and Badger, WI, 304° radials; Badger; INT Badger 121° and Pullman, MI, 282° radials; Pullman;"

V–420 [Revised]

From Bradford, IL, via INT Bradford 033° and Polo, IL, 088° radials; INT Polo 088° and DuPage, IL, 320° radials. From Green Bay, WI; Traverse City, MI; Gaylord, MI; to Alpena, MI.

PART 75—ESTABLISHMENT OF JET ROUTES AND AREA HIGH ROUTES

3. The authority citation for Part 75 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.

§ 75.100 [Amended]

4. Section 75.100 is amended as follows:

J–113 [Removed]

Issued in Washington, DC, on July 23, 1987.

Daniel J. Peterson,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 87–17461 Filed 7–31–87; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 75

[Airspace Docket No. 87–ASO–10]

Alteration of Jet Routes; Florida

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment realigns Jet Routes J–53, J–75 and J–210. The current alignment of these jet routes does not clear the airspace of Restricted Area R–3005A at Fort Stewart, GA, which is active with military training operations from 6 a.m. to midnight, local time, daily. As a result, all aircraft proceeding along these routes must be vectored to the west of Restricted Area R–3005A. This action realigns J–53, J–75 and J–210 to enable flight operations to proceed via flight plan filed, improve safety in that area, and reduce controller workload.

DATES: *Effective date* 0901 U.T.C., September 24, 1987. Comments must be received on or before September 14, 1987.

ADDRESSES: Send comments on the rule in triplicate to: Director, FAA, Southern Region, Attention: Manager, Air Traffic

Division, Docket No. 87-ASO-10, Federal Aviation Administration, P.O. Box 20636, Atlanta, GA 30320.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Lewis W. Still, Airspace Branch (ATO-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9250.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves realigning Jet Routes J-53, J-75 and J-210 located in the vicinity of Jacksonville, FL, and was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to Part 75 of the Federal Aviation Regulations (14 CFR Part 75) is to realign Jet Routes J-53, J-75 and J-210 located in the vicinity of Jacksonville, FL. The current alignment of these jet routes does not clear the boundary of Restricted Area R-3005A at Fort Stewart, GA. R-3005A is utilized for high speed combat maneuvers as well as a wide assortment of military special operations conducted by the 24th Infantry. Activities conducted in that area include battalion size live-fire exercise, Joint Air Attack Team (JAAT) activities in conjunction with A-10 aircraft, parachute attack jumps, numerous and continuous helicopter operations, extensive operations by fighter/attack aircraft and training used in support of the Patriot missile system. This action improves air safety for nonparticipating aircraft and reduces controller workload. Section 75.100 of Part 75 of the Federal Aviation Regulations was republished in Handbook 7400.6C dated January 2, 1987.

Under the circumstances presented, the FAA concludes that there is an immediate need for a regulation to amend the descriptions of Jet Routes J-53, J-75 and J-210 to avoid Restricted Area R-3005A to improve aviation safety. Therefore, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable due to safety requirements for high altitude aircraft operations in the vicinity of Restricted Area R-3005A and are unnecessary because this action is a minor technical amendment in which the public would not be particularly interested.

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. 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 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 75

Aviation safety, Jet routes.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 75 of the Federal Aviation Regulations (14 CFR Part 75) is amended, as follows:

PART 75—ESTABLISHMENT OF JET ROUTES AND AREA HIGH ROUTES

1. The authority citation for Part 75 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.

§ 75.100 [Amended]

2. Section 75.100 is amended as follows:

J-53 [Amended]

By removing the words "Colliers, SC;" and substituting the words "INT Jacksonville 347° and Colliers, SC, 174° radials; Colliers;"

J-75 [Amended]

By removing the words "Columbia, SC;" and substituting the words "INT Taylor 019° and Columbia, SC, 203° radials; Columbia;"

J-210 [Revised]

From INT Savannah, GA, 256° and Vance, SC, 221° radials; Vance; to Wilmington, NC.

Issued in Washington, DC, on July 24, 1987.

Daniel J. Peterson,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 87-17459 Filed 7-31-87; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 83C-0310]

Listing of Color Additives for Coloring Contact Lenses; D&C Yellow No. 10

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 D&C Yellow No. 10 as a color additive in contact lenses. This action is in response to a petition filed by Paragon Optical, Inc. The agency is also announcing that the petitioner has withdrawn its request that FDA also approve the use of D&C Red No. 17 for coloring of contact lenses.

DATES: Effective September 3, 1987, except as to any provisions that may be stayed by the filing of proper objections; objections by September 2, 1987.

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: Mary W. Lipien, 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 October 21, 1983 (48 FR 48870), FDA announced that Paragon Optical, Inc., 947 East Impala Ave., Mesa, AZ 85204, had petitioned (CAP

3C0162; Docket No. 83C–0310) the agency to approve the use of D&C Red No. 17 in coloring contact lenses. An amended notice of filing for Paragon's color additive petition was published in the **Federal Register** of January 6, 1984 (49 FR 937) to announce that the firm was also seeking approval for the use of D&C Yellow No. 10 in coloring contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

Currently, D&C Yellow No. 10 is permanently listed under Part 74 for use in coloring drugs (21 CFR 74.1710) and cosmetics generally (21 CFR 74.2710). This final rule provides for the safe use of D&C Yellow No. 10 in coloring contact lenses as requested by Paragon Optical, Inc., and announces that the petitioner has withdrawn its request for approval of the use of D&C Red No. 17 for coloring contact lenses.

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 contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of D&C Yellow No. 10 as a color additive in contact lenses is subject to this listing requirement. 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 currently before the agency is subject to the statutory listing requirement.

III. The Color Additive

The color additive D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid, with lesser amounts of the disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (CAS Reg. No. 8004–92–0). D&C Yellow No. 10 is manufactured by condensing quinaldine with phthalic anhydride to give the unsulfonated dye, which is then sulfonated with oleum.

IV. Safety Evaluation

FDA concludes from the data submitted in the petition and from other relevant information that the upper limit of exposure to D&C Yellow No. 10 from its use in contact lenses is 280 nanograms per day. The agency-calculated upper limit was based on two factors. First, from information submitted by the petitioner, FDA estimated that the maximum use level of the color additive is 50 micrograms per lens (Ref. 1). Second, the agency made two worst case assumptions: (1) That a user will replace lenses tinted with D&C Yellow No. 10 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 will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst case estimates, exposure to D&C Yellow No. 10 from its use for coloring contact lenses is likely to be far less than 280 nanograms per day.

To establish that the color additive D&C Yellow No. 10 is safe for use in coloring contact lenses, the petitioner conducted an in vitro cytotoxicity study on the color additive using L929 mouse fibroblast cells. The cell cultures were exposed to nine different levels of the color additive ranging from 5 milligrams per milliliter down to 50 picograms per milliliter. Cell growth inhibition over 72 hours of exposure was determined by direct cell count, in addition to total protein analysis. The study demonstrates that the no-effect level for D&C Yellow No. 10 is greater than 50 micrograms per milliliter.

To relate this no-effect concentration for D&C Yellow No. 10 to the maximum concentration level in the eye that would result from the use of this color additive in contact lenses, the agency estimated that the daily exposure of the color additive in each eye (140 nanograms) will be diluted by the average daily volume of tears produced in each eye (1.68 milliliters). This concentration is equal to a maximum daily concentration of 0.083 micrograms of color additive per milliliter in the tear flow and eye area. This concentration is over 600 times less than the no-effect dose for D&C Yellow No. 10 found in the cytotoxicity study.

Based upon the available toxicity data, the small amount of the color additive added to the contact lens, and the agency's exposure calculation, FDA finds that the color additive D&C Yellow No. 10 is safe for use in contact lenses. FDA further concludes that the safety margin is sufficiently large that a limitation on the amount of the color additive that may be present in the lens is not required, beyond the limitation that only the amount necessary to accomplish the intended technical effect may be used.

IV. Certification and Specification Considerations

D&C Yellow No. 10 is currently produced as a certified color additive in accordance with 21 CFR Part 80. The agency concludes that the specifications currently set for D&C Yellow No. 10 under § 74.1710 (21 CFR 74.1710) are adequate to ensure the safe use of this color additive.

V. Conclusion

Based on the data in the petition, safety data in FDA's files on currently regulated uses of this color additive, and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of D&C Yellow No. 10 for coloring contact lenses, and that this color additive is safe for its intended use. In addition, based upon the data it considered, the agency finds that D&C Yellow No. 10 is suitable for use in coloring 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 this color additive in coloring contact lenses is 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 21 CFR 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 amended Notice of Filing for CAP 3C0162, January 6, 1984 (49 FR 937). 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. Reference

The following information has been placed on file at the Dockets Management Branch (address above) and is available for review in that office

between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of February 19, 1985, from Food Additive Chemistry Evaluation Branch to Petitions Control Branch, Re: "Color Additives in Contact Lenses."

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 2, 1987, 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 74

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 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 74 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. In Subpart D by adding new § 74.3710 to read as follows:

§ 74.3710 D&C Yellow No. 10.

(a) *Identity.* The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications.* The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions.* (1) The color additive D&C Yellow No. 10 may be used for coloring 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.

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

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

Dated: July 27, 1987.

John M. Taylor,

Associate Commisssioner for Regulatory Affairs.

[FR Doc. 87–17485 Filed 8–2–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 101

[Docket No. 83N–0280]

Nutrition Labeling of Food; Calorie Content

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to provide for the exclusion of nondigestible dietary fiber when determining the calorie content of a food for nutrition labeling purposes. This action will allow for a more accurate declaration of the available calories in food.

DATES: Effective August 3, 1987. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 101.9 effective on August 3, 1987.

ADDRESS: Requests for single copies of the analytical method may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, or the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF–312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0175.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 13, 1984 (49 FR 32216), as corrected in the **Federal Register** of September 17, 1984 (49 FR 36405), FDA proposed to amend 21 CFR 101.9(c)(3) to provide for the exclusion of nondigestible dietary fiber when determining the calorie content of a food for nutrition labeling purposes. Interested persons were given until October 12, 1984, to comment on the proposal.

Eight comments from trade associations and food manufacturers were received in response to the proposal. All of the comments supported the proposal, but several comments requested minor modifications. These comments and the agency's responses are as follows:

1. One comment from a manufacturer disagreed with the proposed use of the Association of Official Analytical Chemists' (AOAC) method for determining nondigestible dietary fiber and adjusting the calorie declaration. The comment claimed that the AOAC method is not well recognized and is costlier than the method that the manufacturer was using to determine the adjusted calorie declaration for its products. The comment recommended that FDA use the "assimilable carbohydrate" method, in which the adjusted calorie declaration is determined by adding the amount of total starch, total reducing sugars, and sucrose rather than by subtracting the nondigestible dietary fiber from total calories. The comment said that the "assimilable carbohydrate" method would be less costly because the AOAC method cited in the proposal requires an additional analysis to achieve the same results.

The agency has reviewed the method of determining "assimilable carbohydrate" suggested by the comment, and does not agree that this method should be adopted by FDA for regulatory purposes. Although use of the "assimilable carbohydrate" method suggested by the comment may yield results comparable to those achieved with the AOAC method cited in the proposal, the suitability of the method for the analysis of a large variety of foods has not been established. In fact, FDA has very little information on what types of foods have been tested with this method.