

transaction, including, but not limited to, the following:

(1) The proposed effective date of the merger or consolidation.

(2) The proposed name and headquarters location of the continuing or consolidated association.

(3) The names of the persons nominated to serve as directors until the first regular annual meeting of the continuing or consolidated association to be held after the effective date of the merger or consolidation. Any director of a constituent association may be designated in the agreement to serve as a director of the continuing or consolidated association for a period not to exceed his or her current term, after which he or she must stand for reelection. However, the terms of the agreement must provide for the election of at least one director at each annual meeting subsequent to the effective date of the merger or consolidation. The bylaws of the continuing or consolidated association shall reflect the provisions of the merger or consolidation agreement regarding director terms.

(4) A statement of the formula to be used to exchange the stock of the constituent associations for the stock of the continuing or consolidated association. No fractional shares of stock shall be issued.

(5) A statement of any conditions which must be satisfied prior to the effective date of the proposed transaction, including but not limited to approval by stockholders, the supervising bank, and the Farm Credit Administration.

(6) A statement of the representations or warranties, if any, made or to be made by any association, or its officers, directors, or employees that is a party to the proposed transactions.

(7) A statement of the rights of the constituent associations to terminate the agreement before the effective date.

(8) A description of the legal opinions or rulings (including those related to tax matters), if any, that have been obtained or furnished by any party in connection with the proposed transaction. Also, refer to paragraph (a)(5) of this section.

(9) A statement of the authority of those persons designated to carry out the terms of the agreement, including the authority to waive provisions of the agreement and to execute any documents necessary to perfect title, on behalf of the constituent associations.

(b) As an attachment to the agreement, set forth those provisions of the charter and bylaws of the continuing or consolidated association which differ from the existing charter or bylaw provisions of the constituent associations.

§ 611.1124 Territorial adjustments.

Territorial adjustments are subject to the following requirements:

(a) All stockholders, participation certificate holders, and borrowers whose real estate or operations are located in adjusted territories shall be informed in writing of the territory adjustment, and the transfer of their loans to the transferee association. All loans of the transferor association which finance operations located in the transferred territory must be transferred to the transferee association unless otherwise approved by the Farm Credit Administration. Also, the stockholders, participation certificate holders, and borrowers shall be notified of the transfer of their loans and the exchange of related equities for equities of like kinds and amounts in the transferee association. If a like kind of equity is not available in the transferee association, similar equities shall be offered which will not affect adversely the interest of the owner. Each stockholder shall be informed that the latest financial and related information of the associations is available for stockholders' review upon written request.

(b) The Agreement of Transfer of Territory and the Notice of Territory Transfer shall give stockholders 60 days from the date of the notice to notify either association in writing of their decision to decline acceptance of the equities of the transferee association and to remain with the transferor association for normal servicing until the current loan is paid. Any application by the borrower for renewal or for additional credit shall be made to the transferee association, except for those applications permitted under § 614.4070 of this chapter.

(c) This section shall not apply to territorial transfers initiated by order of the Governor of the Farm Credit Administration or to territories transferred due to the liquidation of the transferor association.

§ 611.1125 Association articles and bylaws.

Upon request by a stockholder, the association shall provide a copy of the Articles and bylaws of the association to the stockholder.

4. Sections 611.1150 and 611.1160 of Subpart F are redesignated as a new Subpart H and § 611.1160 is redesignated as § 611.1151, the table of contents to read as follows:

Subpart H—Service Organizations

Sec.

611.1150 Incorporation of service organizations.

Sec.

611.1151 Incorporated and unincorporated service organizations.

Donald E. Wilkinson,

Governor.

[FR Doc. 85-11836 Filed 5-15-85; 8:45 am]

BILLING CODE 6705-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 85-CE-5-AD; Amdt. 39-5064]

Airworthiness Directives; Cessna Models 206, P206, U206, 207 and 210 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new Airworthiness Directive (AD), applicable to certain Cessna Models 206, P206, U206, 207 and 210 Airplanes, which require inspection, repair and/or modification of the engine induction airbox installation. Loss of engine power has resulted from pieces of the lower forward induction airbox separating from the bottom of the duct and being ingested by the engine. This action will preclude engine power loss caused by induction airbox failures.

EFFECTIVE DATE: June 20, 1985.

Compliance: As prescribed in the body of the AD.

ADDRESSES: Cessna Single-Engine Customer care Service Information Letter, SE84-20 dated November 2, 1984, applicable to this AD may be obtained from Cessna Aircraft Company, Piston Aircraft Marketing Division, Post Office Box 1521, Wichita, Kansas 67201. A copy of this information is also contained in the Rules Docket, Office of the Regional Counsel, FAA, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT:

Mr. Paul O. Pendleton, Aerospace Engineer, Aircraft Certification Office, ACE-140W, FAA, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; Telephone 316-946-4427.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an AD requiring inspection, modification and/or replacement of the engine induction airbox installation in certain Cessna 200 airplanes was published in the Federal Register on February 28, 1985 (50 FR 8137). This proposal resulted from three

accidents and several incidents involving failure of the lower skin of the engine induction airbox on normally aspirated (non-turbocharged) airplanes. It has been determined that the lower skin failures resulted in airbox fragments being ingested by the engine which effectively blocks the throttle valve and restricts induction air causing a loss of power. These reports indicate that the cracked conditions are not being detected during normal inspection and/or maintenance of the engine installation. In 1981, Cessna Aircraft Company made a production design change on the induction airbox outboard duct by increasing the lower skin thickness from .032 to .040 inches.

To improve in-service airplane airbox integrity and prevent further failures of the airbox, which may result in engine power loss, Cessna Aircraft Company has issued Single Engine Customer Care Service Information Letter SE84-20 dated November 2, 1984, making available for in-service airplanes the improved induction airbox outboard duct having the increased thickness bottom skin. Since this condition is likely to exist or develop in other airplanes of the same type design, the NPRM proposed visual inspections of the outboard induction air duct for cracks and if found, replacement with a new part per the Service Letter or repair of the existing part on certain Cessna Models 206, P206, U206, 207 and 210 airplanes.

Interested person have been afforded an opportunity to comment on the proposal. Two commenters responded. Both commenters concurred with issuance of the AD in its proposed form. However, one commenter stated that the significance of the problem was not specified or documented in the proposed rule. This commenter also stated that the desired information it obtained from the FAA Aircraft Certification Office should have been included in the NPRM. The FAA believes that justification for the proposed rule was adequately set forth in the Notice. In addition more detailed information was available to any interested party as stated in the Paragraph titled "FOR FURTHER INFORMATION CONTACT:" Which includes the name and phone number of the FAA, ACO and person directly involved with the proposal. Therefore, the FAA does not concur with this comment.

This commenter also disagreed with the FAA position on the cost to the public for AD compliance being only the initial inspection. The repetitive inspections and eventual parts replacement were in the commenters

opinion also included as AD compliance costs. The FAA believes that only the initial inspection is related to the AD compliance because the airplanes may have to have this inspection performed out of sequence with normal inspection intervals. The remaining inspections and eventual parts replacement are (as stated below) expected to be performed in the normal course of proper airplane maintenance and should not be associated with the AD. Therefore, the FAA does not agree with this comment for the reasons stated.

Subsequent to publication of the NPRM, the FAA determined that the repair procedures of paragraph (b) of the proposal should specify a minimum thickness for the repair material. Accordingly, the proposal is adopted without change except for the addition of a minimum thickness specification for the repair procedures.

Discussion

There are approximately 8,000 airplanes affected by the proposed AD at an initial inspection cost of \$15 per airplane. Eventually all airplanes are expected to be modified at an approximate cost of \$300 per airplane. However, only the initial inspection is considered to constitute unscheduled expense as the repetitive inspection and eventual repair or replacement expenses are considered to be absorbed in the normal cost of airplane operation. Accordingly, the estimated total cost to the private sector of compliance with the proposed AD is \$120,000. This cost of compliance with the AD is so small that the expense of compliance will not have a significant financial impact on any small entities operating these airplanes. Therefore, I certify that this action (1) is not a major rule under the provisions of Executive Order 12291, (2) is not a significant rule under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and (3) will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final regulatory evaluation has been prepared and has been placed in the public docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES".

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of the Federal Aviation

Regulations (14 CFR 39.13 is amended by adding the following new AD.

Cessna: Applies to Models 206, U206, U206A, U206B, U206C, U206D, U206E, U206F and U206G, (S/Ns 206-0001 thru U20606065); P206, P206A, P206B, P206C, P206D, and P206E, (S/Ns P206-0001 thru P20600647); 207 and 207A, (S/Ns 20700001 thru 207000681); 210D, 210E, 210F, 210G, 210H, 210J, 210K, 210L, 210M and 210N (S/Ns 21058221 thru 21064226) airplanes certificated in any category which are equipped with Continental Model IO-520-J engines.

Compliance: Required within 100 hours time-in-service after the effective date of this AD and each 100 hours time-in-service thereafter, until modified in accordance with paragraph (b) of the AD. To eliminate the possibility of engine power reduction due to ingestion of pieces of a failed engine induction airbox outboard duct, accomplish the following:

(a) Visually inspect the engine induction airbox outboard duct lower skin for cracks.

(b) If cracks are found, prior to further flight, either replace the induction airbox outboard duct with a Cessna Part Number 1250705-8 duct or repair the skin of the existing duct in accordance with the repair procedures of FAA Advisory Circulars AC 43.13-1A and AC 43.13-2A using material at least .040 inches thick.

(c) An equivalent means of compliance with this AD may be used if approved by the Manager, Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209.

Cessna Single Engine Customer Care Service Information Letter SE84-20 dated November 2, 1984, covers the subject matter of this AD.

(Secs. 313(a), 601 and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and § 11.89 of the Federal Aviation Regulations (14 CFR 11.89))

This amendment becomes effective on June 20, 1985.

Issued in Kansas City, Missouri, on May 6, 1985.

Murray E. Smith

Director, Central Region.

(FR Doc. 85-11792 Filed 5-15-85; 8:45 am)

DBILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket Nos. 84-AWA-13 and 84-AWA-14]

Alteration of VOR Federal Airways

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correction to final rule.

SUMMARY: An error was discovered in the descriptions of new Federal Airways V-554 (50 FR 14089) and V-570 (50 FR 14091) published in the Federal Register

on April 10, 1985. This action corrects those errors.

EFFECTIVE DATE: 0901 GMT, June 6, 1985.

FOR FURTHER INFORMATION CONTACT: Mr. Brent A. Fernald, Airspace and Air Traffic Rules Branch (ATO-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8626.

SUPPLEMENTARY INFORMATION:

History

Federal Register Documents 85-8592 and 85-8593 were published on April 10, 1985, which redesignated, revoked and established new segments of VOR Federal Airways to enhance the traffic flow within the Albuquerque, Fort Worth, Houston and Memphis Air Route Traffic Control Centers' areas. A mistake was discovered in the descriptions of new airways V-554 and V-570, and this action corrects those errors.

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 71

Aviation safety, VOR Federal Airways.

Adoption of the Correction

Accordingly, pursuant to the authority delegated to me, **Federal Register Documents 85-8592 and 85-8593**, as published in the **Federal Register** on April 10, 1985, (50 FR 14089 and 14091) are corrected by revising the descriptions of the following airways:

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

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

2. Section 71.123 is amended as follows:

V-554 [Revised]

From Natchez, MS, via INT Natchez 310° and Monroe, LA, 160° radials; to Monroe.

V-570—[Revised]

From Alexandria, LA, via Natchez, MS; to McComb, MS.

Issued In Washington, D.C., on May 9, 1985.

Shelomo Wugalter,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 85-11789 Filed 5-15-85; 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-0051]

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 an orange dye, C.I. Vat Orange 1 (previously referred to by FDA as dibromodibenzo(b,def)chrysene-7,14-dione), for coloring contact lenses. This action responds to a petition filed by Custom Tint Laboratories, Inc.

DATES: Effective June 17, 1985, except as to any provisions that may be stayed by the filing of proper objections; objections by June 17, 1985.

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: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-334), 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 17, 1983 (48 FR 27834), FDA announced that a color additive petition (CAP 3C0169) had been filed by Custom Tint Laboratories, Inc., 6020 Six Forks Rd., Raleigh, NC 27609, proposing that the color additive regulations be amended to provide for the safe use of six color additives, including dibromodibenzo(b,def)chrysene-7,14-dione, for 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.)

In the **Federal Register** of July 8, 1983 (48 FR 31374), FDA amended the color additive regulations by listing four of the color additives named in the June 17, 1983 notice. In the July 1983 final rule, as corrected in the **Federal Register** of September 28, 1983 (48 FR 44202), FDA deferred final action with respect to the color additives dibromodibenzo(b,def)chrysene-7,14-dione and 6,6'-diethoxy-2,2'-[3H3'H]bibenzo[b]thiophene-3,3'-dione. The agency is again deferring final action on the latter color additive pending receipt and evaluation of additional studies.

After careful consideration of the description of the substance it has referred to as "dibromodibenzo(b,def)chrysene-7,14-dione," FDA has decided that this substance, which imparts a yellowish orange color, is more properly called "C.I. Vat Orange 1." This change in nomenclature is appropriate because the color additive is really a complex mixture with dibromodibenzo(b,def)chrysene-7,14-dione as the principal, but not the only, component. The Colour Index number for C.I. Vat Orange 1 is 59105. This document announces FDA's decision on the safety of the use of C.I. Vat Orange 1.

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 where 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 the color additive presented in the petition now before the agency is subject to this listing requirement. The color additive is added to contact lenses in such a way that at least some of the additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed in 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.

III. Analysis of Data

A. Safety of the Color Additive

1. Legal Standard

Under section 706(b)(4) of the act, the so-called "general safety clause" for color additives, a color additive cannot be listed for a particular use unless the data presented to FDA establish that the color additive is safe for that use. Although what is meant by "safe" is not explained in the general safety clause,

the legislative history makes clear that this word is to have the same meaning for color additives as for food additives.

Safety is defined in the legislative history for the Food Additives Amendment of 1958 as a "reasonable certainty that no harm will result from a proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." S. Rept. 2422, 85th Cong., 2d Sess. 6 (1958). This concept of safety is incorporated in FDA's color additive regulations (21 CFR 70.3(i)). In addition, the anticancer or Delaney Clause of the Color Additive Amendments (section 706(b)(5)(B) of the act) provides that a color additive shall be deemed unsafe and shall not be listed if it is found, after tests that are appropriate for the evaluation of the safety of the additive, to induce cancer in man or animal.

2. Exposure

FDA concludes from the data submitted and from other relevant information that the upper limit of exposure to C.I. Vat Orange 1 from its use in coloring contact lenses is 270 nanograms per day. The agency calculated this upper limit of exposure based on the following factors: First, based on the information submitted by the petitioner, FDA estimated that the maximum use level of C.I. Vat Orange 1 is 50 micrograms per lens (Ref. 1). Second, the agency made two worst-case assumptions: (1) That a user will replace lenses tinted with C.I. Vat Orange 1 once each year with a new pair of lenses tinted with C.I. Vat Orange 1 at the 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 worst case, exposure to C.I. Vat Orange 1 from its use for coloring contact lenses is likely to be far less than 270 nanograms per day.

3. Toxicology

When presented with a substance whose use will result in the extremely low levels of exposure that the agency estimates will result from the use of C.I. Vat Orange 1 in contact lenses, FDA does not ordinarily consider chronic toxicity testing to be necessary to determine the safety of its use (Ref. 2). FDA has not required such testing here, and no data have been submitted that show this color additive to be a carcinogen. Therefore, the Delaney Clause has no application to this proceeding.

FDA did require the petitioner to conduct an in vitro cytotoxicity test on C.I. Vat Orange 1 and primary ocular

irritation studies in rabbits with saline extracts of the tinted lens material. These studies showed no ocular irritation from the saline extracts and no adverse effects in the in vitro cytotoxicity testing.

B. Carcinogenic Constituent

1. C.I. Vat Yellow 4

C.I. Vat Orange 1 may contain a minor amount of the carcinogenic impurity C.I. Vat Yellow 4 (dibenzo(b, def)chrysene-7,14-dione). C.I. Vat Orange 1 is manufactured by dibromination of C.I. Vat Yellow 4. Residual amounts of starting materials, such as C.I. Vat Yellow 4, are commonly found among the constituents of a color additive.

In a bioassay conducted for the Carcinogenesis Testing Program of the National Cancer Institute (NCI) (DHEW Publication No. (NIH) 79-1389), a C.I. Vat Yellow 4 commercial formulation was found to be carcinogenic for male B6C3F1 mice, causing an increased incidence of lymphomas. Under the conditions of the bioassay, the formulation was not carcinogenic for male or female Fischer 344 rats or for female B6C3F1 mice. The tested formulation contained 18.2 percent C.I. Vat Yellow 4.

Among male mice in that bioassay, lymphomas occurred at incidences that were dose related ($p=0.002$). Furthermore, in a direct comparison, the incidence of the tumor in the high-dose group was significantly higher ($p=0.019$) than that in the control group (controls 3/20, or 15 percent; low-dose 7/47, or 15 percent; high-dose 22/50, or 44 percent). The incidence of lymphomas and leukemias in historical-control male B6C3F1 mice at the testing laboratory, NCI Frederick Cancer Research Center, Frederick, MD, was 38/323 (12 percent).

2. Prior Action

In the past, FDA often refused to list a color additive that contained or was expected to contain minor amounts of a carcinogenic chemical, even if the additive as a whole had not been shown to cause cancer. The agency now believes, however, that scientific developments and experience with risk assessment procedures make it possible for FDA to approve the use of an additive that contains a carcinogenic chemical but that has not itself been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6 published in the Federal Register of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it

contains a carcinogenic constituent. Since that decision, FDA has listed, on the same basis, the uses of several other color additives that contain carcinogenic impurities, including the use of D&C Green No. 6 for coloring contact lenses (48 FR 13020; March 29, 1983) and the use of D&C Green No. 5 (47 FR 24278; June 4, 1982) and of D&C Red No. 8 and D&C Red No. 7 (47 FR 57681; December 28, 1982) for coloring drugs and cosmetics. (See also the advance notice of proposed rulemaking published in the Federal Register of April 2, 1982 (47 FR 14464).)

The appropriateness of FDA's decision to list the uses of these color additives is supported by *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has not itself been shown to cause cancer. Relying heavily on the reasoning in the agency's decision, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

The Delaney or anti-cancer clause is not triggered unless the color additive as a whole is found to induce cancer. An additive that has not been shown to induce cancer but that contains a carcinogenic constituent is properly evaluated under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

C. Risk Assessment

Using risk assessment procedures to estimate the upper limit lifetime risk presented by the use of C.I. Vat Orange 1 with the expected impurity, the agency has concluded that the color additive is safe under the proposed conditions of use. The risk evaluation consists of two parts: (1) Estimation of exposure to C.I. Vat Yellow 4 from the use of C.I. Vat Orange 1 for tinting contact lenses and (2) extrapolation of the risk from C.I. Vat Yellow 4 observed in the NCI bioassay of that substance to the conditions of exposure in humans.

As explained above, the agency has estimated that the upper limit of exposure to C.I. Vat Orange 1 from its use for tinting contact lenses is 270 nanograms per day. Based on the reaction mechanism for bromination of aromatic compounds, the agency's experience with other brominated color additives, and the extent of bromination of C.I. Vat Orange 1 (bromine content of C.I. Vat Orange 1 is approximately 28

percent, i.e., approximately 1.7 bromines per molecule), the agency concludes that less than 3 percent residual C.I. Vat Yellow 4 will remain in C.I. Vat Orange 1. Based on the 3 percent maximum residual level for C.I. Vat Yellow 4 and the estimated upper limit exposure to C.I. Vat Orange 1 of 270 nanograms per day, the agency estimates an upper limit lifetime-average individual exposure of 8 nanograms per day for C.I. Vat Yellow 4.

FDA has estimated the risk from the C.I. Vat Yellow 4 impurity from use of C.I. Vat Orange 1 for coloring contact lenses by extrapolating from the risk observed at the level of exposure in the NCI-sponsored animal studies to the very low levels of estimated exposure for humans. In this extrapolation, the agency has used a quantitative risk assessment procedure (linear proportional model) similar to the methods used to examine the risk associated with the presence of minor carcinogenic impurities in D&C Green No. 6 and the other color additives mentioned above. This procedure is not likely to underestimate the actual risk from very low doses. In fact, the estimate of the risk may be exaggerated because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the use of this color additive.

Under this procedure, the upper limit individual lifetime risk from exposure to C.I. Vat Yellow 4 at the level calculated to be the upper limit estimated daily exposure is 3×10^{-11} or less than 1 in 35 billion from the proposed use. Because of numerous conservatism in the exposure estimate, lifetime-averaged individual exposure is expected to be substantially less than the upper limit estimated daily exposure. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to the constituent that results from the use of C.I. Vat Orange 1 in contact lenses.

IV. Certification and Specification Considerations

Based on its consideration of the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of C.I. Vat Orange 1 is not necessary for the protection of the public health.

The agency has considered whether a specification is necessary to control the amount of C.I. Vat Yellow 4 that may exist as an impurity in the color additive. The agency finds that a specification is not necessary because

the upper limit lifetime risk from exposure to the constituent is very low. In addition, exposure to C.I. Vat Orange 1 from use for tinting contact lenses is likely to be substantially less than the estimated upper limit exposure of 270 nanograms per day. Also, the bromination process used to manufacture C.I. Vat Orange 1 (containing approximately 28 percent bromine by weight) is likely to result in substantially less than 3 percent residual C.I. Vat Yellow 4.

V. Conclusion

Based upon the available toxicity data, the small amount of the color additive added to the contact lens, the agency's exposure calculation, and the extremely low risk from the presence of the constituent, FDA finds that the color additive C.I. Vat Orange 1 is safe for use in contact lenses.

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 Center for Food Safety and Applied Nutrition (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 carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting this finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch and can be reviewed by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum for the Record, November 28, 1984, concerning "CAP 3C0169—Exposure Estimate for Vat Orange 1."
2. Kokoski, C. J., "Regulatory Food Additive Technology," presented at the Second International Conference on Safety Evaluation and Regulation of Chemicals, October 24, 1983, Cambridge, MA.

VII. Objections

Any person who will be adversely affected by the regulation may at any

time on or before June 17, 1985 file with the Dockets Management Branch (address above) written objections thereto. Objections shall show wherein 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 objection shall state the issues for the hearing and 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 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. Notice of the filing of objections or lack thereof will be announced by publication 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 citation for Part 73 is revised 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. By adding new § 73.3112 to Subpart D, to read as follows:

§ 73.3112 C.I. Vat Orange 1.

(a) *Identity.* The color additive is C.I. Vat Orange 1, Colour Index No. 59105.

(b) *Uses and restrictions.* (1) The substance 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 (the act) with respect to

the contact lens in which the color additive is used. A person intending to introduce a device containing C.I. Vat Orange 1 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.

Dated: May 10, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-11928 Filed 5-14-85; 10:47 am]

BILLING CODE 4160-01-M

21 CFR Part 81

[Docket No 76N-0366]

Provisional Listing of D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37 For Use in Externally Applied Drugs and Cosmetics; Postponement of Closing Date

Correction

In FR Doc. 85-7768, beginning on page 13017, in the issue of Tuesday, April 2, 1985, make the following correction.

On page 13018 in the second column, in the fourth line of the authority citation, "476" should read "376".

BILLING CODE 1505-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of 13 supplemental new animal drug applications (NADA's) filed for as many sponsoring firms providing for manufacturing premixes containing 5, 10, 20, or 40 grams per pound each of tylosin and sulfamethazine. The

premixes are subsequently used to make finished swine feeds.

EFFECTIVE DATE: May 16, 1985.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: The following 13 firms are sponsors of the indicated supplemental NADA's submitted on their behalf by Elanco Products Co.:

NADA and Sponsoring Firm

1. 97-615 Golden Sun Feeds, Inc., 111 South 5th St., Estherville, IA 51334.
2. 97-981 Quali-Tech, Inc., 318 Lake Hazeline Dr., Chaska, MN 55318.
3. 109-818 International Nutrition, Inc., 6664 L St., Omaha, NE 68117.
4. 122-522 Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
5. 124-391 Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
6. 127-506 Heindold Feeds, Inc., P.O. Box 377, Kouts, IN 46347.
7. 127-507 Carl S. Akey, Inc., P.O. Box 607, Lewisburg, OH 45338.
8. 128-835 Old Monroe Elevator & Supply Co., Inc., Old Monroe, MO 63369.
9. 129-159 Custom Feed Services Corp., 2100 North 13th St., Norfolk, NE 68701.
10. 129-161 Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850.
11. 129-645 Dale Alley Co., P.O. Box 444, 222 Sylvania St., St. Joseph, MO 64502.
12. 129-646 I.M.S., Inc., 13619 Industrial Rd., Omaha, NE 68137.
13. 130-465 Growmark, Inc., 1701 Towanda Ave., Bloomington, IL 61701.

The indicated supplemental NADA's provide for manufacture of premixes containing 5, 10, 20, or 40 grams per pound each of tylosin (as tylosin phosphate) and sulfamethazine intended for subsequent making of finished swine feeds. The resulting feeds will be used to maintain weight gains and feed efficiency in the presence of atrophic rhinitis, lower the incidence and severity of *Bordetella bronchiseptica* rhinitis, prevent swine dysentery (vibronic), and control swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*). The supplemental NADA's are approved and the regulations are amended to reflect the approvals. The basis for approval is discussed in their freedom of information summaries.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support

approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10.

2. In § 558.630 in paragraph (b)(3) by removing "024174" and "046987"; in paragraph (b)(8) by removing "016968"; and by revising paragraph (b)(9) and adding new paragraph (b)(10) to read as follows:

§ 558.630 Tylosin and sulfamethazine.

(b) * * *

(9) To 012286, 022422, and 051359: 5 grams per pound each, paragraph (f)(2)(ii) of this section.

(10) To 016968, 017473, 017790, 018083, 020275, 021780, 024174, 028948, 043727, 043733, 046987, 050568, and 050639: 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

Effective date: May 16, 1985.

Dated: May 7, 1985.

Marvin A. Norcross,
Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-11799 Filed 5-15-85; 8:45 am]

BILLING CODE 4160-01-M