may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

### List of Subjects 14 CFR Part 39

Air transportation, Engines, Aircraft, Aviation safety, Incorporation by reference.

### Adoption of the Amendment

## PART 39—[AMENDED]

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 superseding TAD T84–16–51 with the following new AD:

**Allison Gas Turbine Division, General Motors Corp. (Allison, Detroit Diesel Allison):** Applies to Allison Model 250–C30 and 250–C30S engines installed in Sikorsky Model S–76A helicopters. SIKORSKY AIRCRAFT: Applies to Sikorsky Aircraft Model S–76A helicopters, certificated in any category, and equipped with Allison Model 250–C30/C30S Engines.

Compliance is required as indicated unless already accomplished.

To prevent critical secondary damage in the event of a gas producer turbine rotor burst, accomplish the following:

(a) Within the next 30 days after the effective date of this AD for aircraft in compliance with TAD T84–16–51, and prior to further flight for aircraft not in compliance with TAD T84–16–51, perform the following:

(1) Install the Sikorsky Model S–76A helicopter engine compartment protective shields, P/N 76070–20077–013 or P/N 76070–20077–014, in accordance with Sikorsky Alert Service Bulletin 76–71–7 dated November 9, 1984, or FAA-approved equivalent; and concurrently,

(2) Install Allison first stage turbine wheel external energy absorbing rings, P/N 23031910, L.H. and 23031920, R.H. around the Allison Model 250–C30 and –C30S engines in accordance with Allison Commercial Engine Alert Bulletin CEB–A–72–3124 dated November 15, 1984, and prerequisite CEB–A–72–3125 date November 15, 1984, and Sikorsky Alert Service Bulletin 76–71–7, dated November 9, 1984, or FAA-approved equivalents; or, install an Allison first stage turbine wheel internal energy absorbing ring P/N 23031909, in accordance with Allison Commercial Engine Alert Bulletin CEB–A–72–3128 dated November 15, 1984, and Sikorsky Alert Service Bulletin 76–71–7 dated November 9, 1984, or FAA-approved equivalents.

(b) Within the next 25 hours time in service after compliance with (a), above, and thereafter at intervals not to exceed 25 hours time in service, inspect the Sikorsky Model S–76A helicopter engine compartment protective shields in accordance with Chapter 5 of Sikorsky Airworthiness and Inspection Requirements Manual, Publication No. SA 4047–76–2–1, dated November 12, 1984, or FAA-approved equivalent.

(c) Update the engine to the "Allison Assured Engine" configuration at the next repair/overhaul shop visit, but not later than March 30, 1986, in accordance with Allison Commercial Service Letter, CSL–3068, dated October 1, 1984, or FAA approved equivalent.

(d) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate helicopters to a base for accomplishment of this AD.

(e) Upon request, an equivalent means of compliance with the requirements of this AD may be approved by the Manager, Chicago Aircraft Certification Office, FAA, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

(f) Upon request, an FAA maintenance inspector may adjust the compliance schedule in this AD if the request contains data to justify the increase and it is approved by the Manager, Chicago Aircraft Certification Office, FAA, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to Allison Gas Turbine Division, General Motors Corporation, P.O. Box 420, Indianapolis, Indiana 46206–0420; and Sikorsky Aircraft, Division of United Technologies Corporation, North Main Street, Stratford, Connecticut 06601. These documents also may be examined at the Office of the Regional Counsel, FAA, ATTN: Rules Docket No. 84–ANE–21, 12 New England Executive Park, Burlington, Massachusetts 01803, weekdays, except federal holidays, between 8:00 a.m. and 4:30 p.m.

This AD supersedes TAD T84–16–51 issued August 16, 1984.

This amendment becomes effective December 10, 1984.

(Secs. 313(a), 601 and 603, Federal Aviation Act of 1958 as amended (49 U.S.C. 1354(a), 1421, and 1423); 40 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12 1983); 14 CFR 11.89)

Issued in Burlington, Massachusetts, on November 21, 1984.

**Robert E. Whittington,**

*Director, New England Region.*

Issued in Fort Worth, Texas, on November 28, 1984.

**C.R. Melugin, Jr.,**

*Director, Southwest Region.*

[FR Doc. 84–32046 Filed 12–10–84; 10:41 am]

BILLING CODE 4910–13–M

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## 14 CFR Part 71

**[Airspace Docket No. 84–AWA–1]**

## Alteration of VOR Federal Airways; Montgomery, AL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment alters the descriptions of several Federal Airways located in the vicinity of Montgomery, AL, by revoking some airway segments and renumbering other airway segments. This action supports the FAA's agreement with the International Civil Aviation Organization (ICAO) to eliminate all alternate airway designations from the National Airspace System.

**EFFECTIVE DATE:** 0901 GMT, February 14, 1985.

**FOR FURTHER INFORMATION CONTACT:** Lewis W. Still, 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

On August 22, 1984, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to alter the description of several airway segments located in the vicinity of Montgomery, AL (49 FR 33274). This amendment deletes several alternate airways and revokes segments of several airways. 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. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.123 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6 dated January 3, 1984.

### The Rule

This amendment to Part 71 of the Federal Aviation Regulations alters the descriptions of several VOR Federal Airways located in the vicinity of Montgomery, AL, by revoking some airway segments and renumbering other segments. This action supports the FAA's agreement with ICAO to eliminate all alternate airway designations from the National Airspace System.

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

VOR Federal Airways, Aviation safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as amended (49 FR 6706), is further amended, as follows:

#### V-1 [Amended]

By removing the words "Kinston, including an east alternate from Grand Strand to Kinston via Wilmington, NC;" and substituting the words "Kinston;"

#### V-70 [Amended]

By removing all the words after "to Allendale, SC." and substituting the words "From Grand Strand, SC; Wilmington, NC; to Kinston, NC. The airspace within Mexico is excluded."

#### V-3 [Amended]

By removing the words "including a W alternate via INT Melbourne 322° and Ormond Beach 211° radials" and the words "The portion outside the United States has no upper limit except that portion of the E alternate between Jacksonville and Savannah extends up to but not including 18,000 feet MSL."

#### V-437 [Amended]

By removing the words "From Ormond Beach, FL," and substituting the words "From Melbourne, FL; INT Melbourne 322° and Ormond Beach, FL, 211° radials; Ormond Beach;"

#### V-7 [Amended]

By removing all the words before "Central City, KY" and substituting the words "From Biscayne Bay, FL, via Fort Myers, FL; Lakeland, FL; Cross City, FL; Tallahassee, FL; Wiregrass, AL; INT Wiregrass 333° and Montgomery, AL, 129° radials; Montgomery; Vulcan, AL; Muscle Shoals, AL; Graham, TN;"

#### V-521 [New]

From Miami, FL, via INT Miami 337° and Fort Myers, FL, 101° radials; Fort Myers; INT Fort Myers 022° and Lakeland, FL, 154° radials; Lakeland; Cross City, FL; INT Cross City 287° and Marianna, FL, 141° radials; Marianna; Wiregrass, AL; INT Wiregrass 333° and Montgomery, AL, 129° radials; Montgomery; INT Montgomery 357° and Vulcan, AL, 139° radials; Vulcan.

#### V-16 [Amended]

By removing the words "Nashville, TN, including a north alternate from Jacks Creek to Nashville via INT Jacks Creek 049° and Nashville 286° radials; INT Nashville 102° and Hinch Mountain, TN, 285° radials; Hinch Mountain; including a north alternate via INT Nashville 085° and Hinch Mountain 306° radials; Knoxville, TN, including a S alternate via INT Hinch Mountain 100° and Knoxville 243° radials; Holston Mountain, TN, including a S alternate from Knoxville to Holston Mountain via Snowbird, TN, Pulaski, VA, including a N alternate from Knoxville to Pulaski via INT Knoxville 050° and Glade Spring, VA, 246° radials and Glade Spring;" and substituting the words "Nashville, TN; INT Nashville 102° and Hinch Mountain, TN, 285° radials; Hinch Mountain; Knoxville, TN; Holston Mountain, TN; Pulaski, VA;"

#### V-136 [Amended]

By removing the words "From Pulaski, VA," and substituting the words "From Nashville, TN, INT Nashville 085° and Hinch Mountain, TN, 306° radials; Hinch Mountain, INT Hinch Mountain 100° and Knoxville 243° radials; Knoxville, TN; Snowbird, TN; Holston Mountain, TN; Pulaski, VA;"

#### V-466 [New]

From Knoxville, TN, via INT Knoxville 050° and Glade Spring, VA, 246° radials; Glade Spring; to Pulaski, VA.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.69)

Issued in Washington, D.C., on December 5, 1984.

**John W. Baier,**

*Acting Manager, Airspace-Rules and Aeronautical Information Division.*

[FR Doc. 84-32425 Filed 12-12-84; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Parts 182 and 184

[Docket No. 83N-0153]

## GRAS Status of Linoleic Acid

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is affirming that linoleic acid is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

**EFFECTIVE DATE:** January 14, 1985.

**FOR FURTHER INFORMATION CONTACT:** John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-5487.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 3, 1983 (48 FR 45121), FDA published a proposal to affirm that linoleic acid is GRAS for use as a direct human food ingredient. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on linoleic acid are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of linoleic acid, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients other than the proposed conditions of use. Persons asserting additional or extended use in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of these sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of linoleic acid recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate. FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for linoleic acid were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of linoleic acid under conditions different from those set forth in this final rule has been waived.

One comment from a chemical firm was received in response to the proposal. The comment raised several issues. A summary of the issues and the agency's response follows:

1. The comment alleges that the proposed rule is confusing as to its intent.

The agency has reviewed this allegation and disagrees that any confusion exists as to the intent of the proposal. FDA published the proposal to announce the results of the agency's safety evaluation and its tentative conclusions about the GRAS status of the use of linoleic acid.

2. The comment criticized the preamble to the proposed rule for listing coconut oil as a source of linoleic acid. The comment points out that the linoleic acid content of coconut oil is only about 2 percent.

The agency agrees with the comment's concern about mentioning coconut oil as a source of linoleic acid. Coconut oil contains only low levels of linoleic acid and is not known as a commercial source of linoleic acid. FDA mentioned coconut oil in the preamble to the proposal solely as an example of a potential source of linoleic acid. The regulation does not mention any specific source of linoleic acid. Because the objection raised concerns regarding statements in the preamble and not in the regulation, the agency has not modified the regulation in response to this comment.

3. Additionally, the comment alleges that the preamble to the proposal appears to endorse the acceptability of one fat over another. The comment alleged that, as a result, the preamble has the effect of endorsing only a select group of triglycerides for use in food.

The agency disagrees with the comment's interpretation of the preamble. The preamble merely listed as examples some of the sources of oils that are known to have high linoleic acid content and that are potential sources of linoleic acid.

4. The comment states further that free fatty acids including linoleic acid are commercially prepared by treating the triglycerides of edible fats or oils with water under high temperature and pressure. The comment criticizes the low temperature, low pressure method described in the proposal as not being commercially viable. The comment asserts that the method of manufacture included in the proposal is too restrictive and has the potential to limit large volume fatty acid producers as suppliers of edible linoleic acid.

The agency agrees that there are other commercial methods for production of fatty acids than that described in the proposal. The agency did not cite these other methods in the proposal, but they include low pressure splitting with catalyst, medium pressure splitting with catalyst, continuous high pressure counter current splitting, and the Twitchell process. The agency also agrees with the comment that low pressure, low temperature methods of production of fatty acids may not be commercially viable. Therefore, FDA has modified the final rule to include the various processes known to be commercially viable.

Because no food-grade specifications exist for linoleic acid at the present time, the agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for this ingredient. If acceptable specifications are developed, the agency will incorporate them into this regulation at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if commercial linoleic acid complies with the description in the regulation, meets the purity specifications listed in § 172.860(b) (21 CFR 172.860(b)), and otherwise is of a purity suitable for its intended use in accordance with § 182.1(b)(3) (21 CFR 182.1(b)(3)).

The agency has previously determined under 21 CFR 25.24(d)(6) (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. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

**List of Subjects**

*21 CFR Part 182*

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

*21 CFR Part 184*

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

## PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

**§ 182.8065 [Removed]**

1. Part 182 is amended by removing § 182.8065 *Linoleic acid.*

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

2. Part 184 is amended by adding new § 184.1065 to read as follows:

**§ 184.1065 Linoleic acid.**

(a) Linoleic acid ((Z, Z)–9, 12-octadecadienoic acid ($C_{17}H_{31}COOH$) (CAS Reg. No. 60–33–3)), a straight chain unsaturated fatty acid with a molecular weight of 280.5, is a colorless oil at room temperature. Linoleic acid may be prepared from edible fats and oils by various methods including hydrolysis and saponification, the Twitchell method, low pressure splitting with catalyst, continuous high pressure counter current splitting, and medium pressure autoclave splitting with catalyst.

(b) FDA is developing food-grade specifications for linoleic acid in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use. The ingredient must also meet the specifications in § 172.860(b) of this chapter.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may be used in infant formula in

accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

*Effective date.* This regulation shall be effective January 14, 1985.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: December 6, 1984.

**Joseph P. Hile,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 84-32421 Filed 12-12-84; 8:45 am]

**BILLING CODE 4160-01-M**

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**21 CFR Part 510**

**[Docket No. 83N-0340]**

## New Animal Drugs; Corticosteroid-Containing Animal Drugs

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulation concerning labeling requirements for use of corticosteroid-containing animal drugs to delete intramammary products, add ophthalmic products, and add an additional warning concerning certain congenital anomalies. This action is taken because the agency has received reports of adverse reactions associated with the use of corticosteroids in animals. This action follows publication of a proposed rule and opportunity for comment.

**DATE:** Effective June 11, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce.

**ADDRESS:** Supplemental NADA's should be submitted to the Division of Surveillance, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, Rm. 7B–31, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** David N. Scarr, Center for Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3183.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 18, 1970 (35 FR 11556), FDA published a regulation providing for certain labeling requirements concerning oral and parenteral use of corticosteroid-containing animal drugs (21 CFR 135.101 recodified as 21 CFR 510.410). In the **Federal Register** of November 16, 1972 (37 FR 24343), FDA amended that regulation to include intramammary products.

FDA has received additional information consisting of published literature and adverse reaction reports concerning congenital anomalies associated with the animal use of corticosteroids. In addition, the results of a published study indicated the need for warning statements relating to use of ophthalmic preparations containing corticosteroids. FDA has also determined that intramammary products no longer include steroids in their formulations. Therefore, a warning for that use is no longer needed.

FDA published a proposed rule in the **Federal Register** of May 23, 1984 (49 FR 21767) to amend the regulation by adding a warning concerning congenital anomalies, removing intramammary products, and adding ophthalmic products. Comments were requested by July 23, 1984. No comments have been received.

Therefore, the agency is amending the regulation based upon this proposal, effective June 11, 1985. Any oral, parenteral, or ophthalmic corticosteroid-containing animal drug initially introduced or initially delivered for introduction into interstate commerce after that date must comply with the amended regulation. Supplements to NADA's should be submitted to the Division of Surveillance, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, Rm. 7B–31, 5600 Fishers Lane, Rockville, MD 20857, no later than June 11, 1985. Revised labeling that complies with this regulation may be placed into effect prior to approval.

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(b)(13) (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.

FDA has determined that this action is not a major rule as defined in Executive Order 12291 and certifies in accordance with section 605(b) of the Regulatory Flexibility Act (94 Stat. 1168) that the regulation will not have a significant economic impact on a substantial number of small entities. FDA estimates that approximately 22 firms manufacture or distribute approximately 50 to 70 corticosteroid-containing animal drug products. These firms will be required to revise their labeling. These revisions will cost approximately $120,000. A copy of the economic and regulatory assessment supporting these statements is on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

Copies of information supporting this action are on file with the Dockets Management Branch (address above). The file is available for public inspection under Docket No. 83N–0340.

**List of Subjects in 21 CFR Part 510**

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 510 is amended by revising § 510.410 to read as follows:

## PART 510—NEW ANIMAL DRUGS

**§ 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.**

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

*Warning:* Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

*Effective date.* This rule is effective June 11, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce.

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C.) 360b, 371(a)))

Dated: November 27, 1984.

Mark Novitch,

*Deputy Commissioner of Food and Drugs.*

[FR Doc. 84–32422 Filed 12-12-84; 8:45 am]

BILLING CODE 4160-01-M

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## DEPARTMENT OF STATE

### 22 CFR Parts 120, 121, 124, and 130

[Departmental Reg. 108.840]

### Revision of the International Traffic in Arms Regulations

*Correction*

In FR Doc. 84–31706 beginning on page 47682 in the issue of Thursday, December 6, 1984, make the following corrections:

**§ 120.10 [Corrected]**

1. On page 47685, in the first column, in § 120.10, four lines from the bottom of the page, "payland" should read "payload".

**§ 120.12 [Corrected]**

2. On the same page, in the middle column, in § 120.12, the last line, "articile" should read "article".

**§ 121.1 [Corrected]**

3. On page 47686, in the third column, in § 121.1, under **Category III—Ammunition**, in paragraph (a), the last line, "211.6" should read "121.6".

4. On page 47688, in the first column, under **Category XII—Fire Control, Range Finder, Optical and Guidance and Control Equipment**, in paragraph (a), the sixth line, "equipments" should read "equipment".

**§ 121.15 [Corrected]**

5. On page 47690, in the third column, in § 121.15(b)(2)(i), the first line, "SSR" should read "ASR".

**§ 124.3 [Corrected]**

6. On page 47696, in the middle column, in § 124.3(b)(1), the last line, "limitaitions" should read "limitations".

7. In the same section, in paragraph (b)(2), the fifth line, "othe" should read "other".

**§ 124.10 [Corrected]**

8. On page 47697, in the third column, in § 124.10(a)(6), the paragraph in small print should have quotation marks at the end of the paragraph.

**§ 124.14 [Corrected]**

9. On page 47699, in the middle column, in § 124.14(c)(7), the paragraph in small print should have quotation marks at the end of the paragraph.

**§ 130.10 [Corrected]**

10. On page 47711, in the middle column, in § 130.10(c)(2), the sentence beginning "In lieu of reporting" should have appeared flush to the left margin.

BILLING CODE 1505-01-M

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 301

[T.D. 7996]

### Procedure and Administration; Special Rules for Certain Refund Claims Treated as Special Enforcement Areas Under Rules for Consolidated Partnership Proceedings

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document provides temporary regulations on procedure and administration relating to special enforcement areas under the rules for consolidated partnership proceedings. The Tax Equity and Fiscal Responsibility Act of 1982 amended the tax law to allow for consolidated administrative and judicial proceedings to determine the tax treatment of partnership items at the partnership level rather than at the partner level. That Act also authorized special rules for areas that present special enforcement considerations. The regulations provide guidance to Internal Revenue Service personnel and partners with respect to these new provisions.

**DATES:** Effective date: December 10, 1984. These temporary regulations are applicable with respect to certain applications for tentative carryback and refund adjustments ("quick refunds") and claims for credit or refund filed after December 10, 1984.

**FOR FURTHER INFORMATION CONTACT:** Nerman Dobynes Hubbard of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, D.C. 20224 (Attention: CC:LR:T) (202-566-3297, not a toll-free call).

**SUPPLEMENTARY INFORMATION:**

**Background**

This document contains amendments to the Regulations on Procedure and Administration (26 CFR Part 301) under section 6231(c) of the Internal Revenue Code of 1954. The amendments are issued under the authority contained in section 6231(c) (1) and (3) of the Internal Revenue Code of 1954 (96 Stat. 665, 26 U.S.C. 6231(c) (1) and (3)). These temporary regulations will remain in effect until superseded by later regulations on the same subject.

**Explanation of Provisions**

Ordinarily under the partnership audit rules (Code sections 6221 through 6233), the Internal Revenue Service may adjust the treatment of partnership items by a partner who reported those items consistently with the treatment of those items on the partnership return only through partnership-level proceedings. No matter how expeditiously the Service conducts a partnership proceeding, however, in most cases the Service will not be in a position for at least a year to make any assessments as a result of adjustments to partnership items through partnership proceedings.

The Service is concerned about the increase in abusive tax shelters that generate refunds for taxpayers based on losses, deduction, or credits of a partnership. Paying out refunds attributable to partnership losses, deductions, or credits when the available relevant information indicates that those losses, deductions, or credits are attributable to an abusive tax shelter and consequently highly likely to be excessive will impose a heavy burden on the collection resources of the Service. In some cases, the amounts refunded will be uncollectible because the taxpayers who received the refunds will have no assets at the time that the final determination of liability and the demand for payment are made; in other cases, the Service will have to levy on the property of taxpayers who do not have enough cash to pay the tax due.

Because of these concerns, the Commissioner has determined that "special enforcement considerations," within the meaning of section 6231(c)(1), are present in the case of certain applications under section 6411 (relating to tentative carryback and refund adjustments) and claims for credit or refund based on losses, deductions, or credits of a partnership. Special enforcement considerations exist in these cases if the Commissioner or his delegate determines, after review of the available relevant information, that it is highly likely that a person described in section 6700(a)(1) made, with respect to the partnership from which the losses, deductions, or credits arise, (1) a gross valuation overstatement, or (2) a false or fraudulent statement with respect to the tax benefits to be secured by reason of holding an interest in the partnership, that would be subject to a penalty under section 6700 (relating to penalty for promoting abusive tax shelters, etc.). These regulations apply only with respect to an application or claim based upon the original reporting on the partner's income tax return of partnership losses, deductions, or credits. Thus, the regulations do not apply to a request for administrative adjustment under section 6227 through which a partner seeks to change the partner's reporting of partnership items on the partner's income tax return (or on an earlier request for administrative adjustment).

Section 6231(c)(3) authorizes regulations to prescribe special rules to achieve the objectives of the partnership audit legislation in any special enforcement area. Because one of the principal purposes of the legislation is to provide for more efficient use of the Service's resources by reducing multiple proceedings with respect to partnership items, the temporary regulations permit the Service to avoid later collection problems by offsetting or suspending any refund attributable to items from a partnership described above without removing the partner from partnership-level proceedings. The partnership items of the partner remain subject to adjustment through partnership-level proceedings unless the partner exercises a limited right to treat those items as nonpartnership items.

In the case of applications under section 6411, the regulations override the restriction on assessments under section 6225. The regulations permit the Service to make an assessment that would, but for the restriction set out in section 6225, be permitted under section 6213(b)(3) (relating to assessments arising out of tentative carryback or refund adjustments) with respect to any amount applied, credited, or refunded as a result of an application under section 6411 that is subject to these regulations. Thus, the regulations provide that, notwithstanding section 6225, an assessment under section 6213(b)(3) with respect to any amount applied, credited, or refunded as a result of an application under section 6411 may be made before there is a final partnership-level determination with respect to the losses, deductions, or credits on which the application is based.

The regulations also permit the Service to suspend certain refunds attributable to abusive tax shelter partnerships. Thus, the regulations provide that the Service may mail to the partner filing a claim for a credit or refund which presents special enforcement considerations a notice stating that no action will be taken on the partner's claim until the completion of partnership-level proceedings.

Under the regulations, a partner to whom the Service mails a notice of assessment or of suspension generally remains subject to the partnership audit rules. To insure that the partner is not denied access to a court with respect to the items in dispute for an unreasonable period of time, however, the regulations provide that the partner may in certain circumstances elect to have all partnership items for the partnership taxable year in which the items at issue arose treated as nonpartnership items. A partner making this election will enjoy the same rights with respect to items arising from the partnership as the partner enjoys with respect to other nonpartnership items. The partner may, for example, file a refund suit if the Service fails to grant a claim for refund with respect to those items within 6 months. The election is made by filing a statement with the Internal Revenue Service office that mailed the notice. The statement may be filed at any time (1) after the date which is one year after the date on which the partnership return was filed for the partnership taxable year in which the items at issue arose, and (2) before the date on which the Service mails to the tax matters partner the notice of final partnership administrative adjustment for that partnership taxable year.

Under the temporary regulations, the Service is able to avoid the risk that amounts refunded might later be uncollectible. If, as a result of either partnership-level or separate proceedings, the partnership losses, deductions, or credits giving rise to the refund are determined to be allowable, the refund will be made with interest.

### Non-Applicability of Executive Order 12291

The Treasury Department has determined that this temporary regulation is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis is therefore not required.

### Regulatory Flexibility Act

No general notice of proposed rulemaking is required by 5 U.S.C. 553(b) for temporary regulations. Accordingly, the Regulatory Flexibility Act does not apply and no Regulatory Flexibility Analysis is required for this rule.

### Drafting Information

The principal author of these regulations is Nerman Dobynes Hubbard of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

### List of Subjects in 26 CFR Part 301

Administrative practice and procedure, Bankruptcy, Courts, Crime, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income, Investigations, Law enforcement, Penalties, Pensions, Statistics, Taxes, Disclosure of information, Filing requirements.

### Adoption of Amendments to the Regulations

Accordingly, the Regulations on Procedure and Administration (26 CFR Part 301) are amended as follows:

## PART 301—[AMENDED]

**Paragraph 1.** A new § 301.6231(c)-1T is added in the appropriate place to read as follows:

**§ 301.6231(c)-1T Special rules for certain applications for tentative carryback and refund adjustments based on partnership losses, deductions, or credits (temporary).**

(a) *Applications subject to this section.* This section applies in the case of an application under section 6411 (relating to tentative carryback and refund adjustments) based on losses, deductions, or credits of a partnership if the Commissioner or his delegate determines, after review of the available relevant information, that it is highly likely that a person described in section 6700(a)(1) made, with respect to the partnership—

(1) A gross valuation overstatement, or

(2) A false or fraudulent statement with respect to the tax benefits to be secured by reason of holding an interest in the partnership, that would be subject to a penalty under section 6700 (relating to penalty for promoting abusive tax shelters, etc.). This section applies only with respect to an application based upon the original reporting on the partner's income tax return of

partnership losses, deductions, or credits. Thus, this section does not apply to a request for administrative adjustment under section 6227 through which a partner seeks to change the partner's reporting of partnership items on the partner's income tax return (or on an earlier request for administrative adjustment).

(b) *Determination of special enforcement area.* In the case of an application under section 6411 described in paragraph (a) of this section, precluding an assessment under section 6225 that would be permitted under section 6213(b)(3) (relating to assessments arising out of tentative carry back or refund adjustments) with respect to any amount applied, credited, or refunded as a result of the application may encourage the proliferation of abusive tax shelter partnerships and make the eventual collection of taxes due more difficult. Consequently, the Commissioner hereby determines that such applications present special enforcement considerations within the meaning of section 6231(c)(1)(E).

(c) *Assessment permitted under section 6213(b)(3).* Notwithstanding section 6225 (relating to restrictions on assessment with respect to partnership items), an assessment that would be permitted under section 6213(b)(3) with respect to any amount applied, credited, or refunded as a result of an application described in paragraph (a) of this section may be made before there is a final partnership-level determination with respect to the losses, deductions, or credits on which the application is based. As provided in section 6213(b)(1), the Service shall mail notice of any such assessment to the partner filing the application. The notice shall also inform the partner of the partner's limited right to elect to treat items as nonpartnership items as provided in paragraph (d) of this section.

(d) *Limited right to elect to treat items as nonpartnership items*—(1) *In general.* A partner to whom the Service mails notice of an assessment under paragraph (c) of this section may elect in accordance with this paragraph (d) to have all partnership items for the partnership taxable year in which the losses, deductions, or credits at issue arose treated as nonpartnership items.

(2) *Time and place of making election.* The election shall be made by filing a statement with the Internal Revenue Service office that mailed the notice of assessment. The statement may be filed at any time—

(i) After the date which is one year after the date on which the partnership return was filed for the partnership taxable year in which the items at issue arose, and

(ii) Before the date on which the Service mails to the tax matters partner the notice of final partnership administrative adjustment for the partnership taxable year in which the items at issue arose.

For purposes of this paragraph (d)(2), a partnership return filed before the last day prescribed by law for its filing (determined without regard to extensions) shall be treated as filed on that last day.

(3) *Contents of the statement.* The statement shall—

(i) Be clearly identified as an election to have partnership items treated as nonpartnership items because of notification of an assessment under section 6213(b)(3),

(ii) Identify the partnership by name, address, and taxpayer identification number,

(iii) Identify the partner making the election by name, address, and taxpayer identification number,

(iv) Specify and partnership taxable year to which the election applies, and

(v) Be signed by the partner making the election.

(e) *Effective date.* This section applies with respect to any application described in paragraph (a) of this section that is filed after December 10, 1984.

**Par. 2.** A new § 301.6231(c)–2 T is added in the appropriate place to read as follows:

**§ 301.6231(c)–2 T Special rules for certain refund claims based on losses, deductions, or credits from abusive tax shelter partnerships (Temporary).**

(a) *Claims subject to this section.* This section applies in the case of a claim for credit or refund based on losses, deductions or credits of a partnership if the Commissioner or his delegate determines, after review of available relevant information, that it is highly likely that a person described in section 6700(a)(1) made, with respect to the partnership—

(1) A gross valuation overstatement, or

(2) A false or fraudulent statement with respect to the tax benefits to be secured by reason of holding an interest in the partnership, that would be subject to a penalty under section 6700 (relating to penalty for promoting abusive tax shelters, etc.). This section applies only with respect to a claim that is based upon the partner's original reporting on the partner's income tax return of partnership losses, deductions, or credits. Thus, this section does not apply to a request for administrative adjustment under section 6227 through which a partner seeks to change the partner's reporting of partnership items on the partner's income tax return (or on an earlier request for administrative adjustment). For purposes of this section, any income tax return requesting a credit or refund shall be treated as a claim for a credit or refund.

(b) *Determination of special enforcement area.* Granting a claim for credit or refund described in paragraph (a) of this section may encourage the proliferation of abusive tax shelter partnerships and make the eventual collection of taxes due more difficult. Consequently, the Commissioner hereby determines that such claims present special enforcement considerations within the meaning of section 6231(c)(1)(E).

(c) *Action on refund claims suspended.* In the case of a claim described in paragraph (a) of this section, the Service may mail to the partner filing the claim a notice stating that no action will be taken on the partner's claim until the completion of partnership-level proceedings. The notice shall also inform the partner of the partner's limited right to elect to treat items as nonpartnership items as provided in paragraph (d) of this section.

(d) *Limited right to elect to treat items as nonpartnership items*—(1) *In general.* A partner to whom the Service mails a notice of suspension of action on a refund claim under paragraph (c) of this section may elect in accordance with this paragraph (d) to have all partnership items for the partnership taxable year in which the losses, deductions, or credits at issue arose treated as nonpartnership items.

(2) *Time and place of making election.* The election shall be made by filing a statement with the Internal Revenue Service office that mailed the notice of suspension. The statement may be filed at any time—

(i) After the date which is one year after the date on which the partnership return was filed for the partnership taxable year in which the items at issue arose, and

(ii) Before the date on which the Service mails to the tax matters partner the notice of final partnership administrative adjustment for the partnership taxable year in which the items at issue arose.

For purposes of this paragraph (d)(2), a partnership return filed before the last day prescribed by law for its filing (determined without regard to extensions) shall be treated as filed on that last day.

(3) *Contents of the statement.* The statement shall—

(i) Be clearly identified as an election to have partnership items treated as nonpartnership items because of notification of suspension of action on a refund claim,

(ii) Identify the partnership by name, address, and taxpayer identification number,

(iii) Identify the partner making the election by name, address, and taxpayer identification number,

(iv) Specify the partnership taxable year to which the election applies, and

(v) Be signed by the partner making the election.

(e) *Effective date.* This section applies with respect to any claim described in paragraph (a) of this section that is filed after December 10, 1984.

There is need for immediate guidance with respect to the subject matter of this Treasury decision. For this reason, it is found impracticable to issue this Treasury decision with notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

This Treasury decision is issued under the authority contained in section 6231(c) (1) and (3) of the Internal Revenue Code of 1954 (96 Stat. 665, 26 U.S.C. 6231(c) (1) and (3)).

Roscoe L. Egger, Jr.,

*Commissioner of Internal Revenue.*

Approved: December 7, 1984.

Ronald A. Pearlman,

*Acting Assistant Secretary of Treasury.*

[FR Doc. 84-32473 Filed 12-10-84; 1:30 pm]

BILLING CODE 4830-01-M

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## DEPARTMENT OF DEFENSE

## Department of the Navy

## 32 CFR Part 706

## Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

**AGENCY:** Department of the Navy, DOD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Secretary of the Navy has determined that USS FORD (FFG 54) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special function as a naval frigate. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

**EFFECTIVE DATE:** November 20, 1984.

**FOR FURTHER INFORMATION CONTACT:** Captain Richard J. McCarthy, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (202) 325-9744.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority granted in 33 U.S.C. 1605 and Executive Order 11964, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Secretary of the Navy has certified that USS FORD (FFG 54) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS: Rule 21(a) regarding the arc of visibility of its forward masthead light; Annex I, section 2(a)(i), regarding the height above the hull of its forward masthead light; and Annex I, section 3(b), regarding the horizontal relationship of its sidelights to its forward masthead light, without interfering with its special function as a Navy frigate. The Secretary of the Navy has also certified that the above-mentioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements. Notice is also provided to the effect that USS FORD (FFG 54) is a member of the FFG 7 class of ships for which certain exemptions, pursuant to 72 COLREGS, Rule 38, have been previously authorized by the Secretary of the Navy. The exemptions pertaining to that class, found in the existing tables of § 706.3, are equally applicable to this ship.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this ship in a manner differently from that prescribed herein will adversely affect the ship's ability to perform its military functions.

### List of Subjects in 32 CFR Part 706

Marine safety, Navigation (Water), and Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

## PART 706—[AMENDED]

### § 706.2 [Amended]

1. Table One of § 706.2 is amended by adding the following entry as follows to indicate the certifications issued by the Secretary of the Navy:

| Vessel | Number | Distance in meters of forward masthead light below minimum required height. Section 2(a)(i), annex I |
|---|---|---|
| USS FORD | FFG 54 | 1.6 |

2. Table Four of § 706.2 is amended by adding to the existing paragraph 8 the following vessel for which navigational light certification is herewith issued by the Secretary of the Navy:

USS FORD........ FFG 54

3. Table Four of § 706.2 is amended by adding to the existing paragraph 9 the following vessel for which navigational light certification is herewith issued by the Secretary of the Navy:

| Vessel | Number | Distance of side lights forward of masthead lights in meters |
|---|---|---|
| USS FORD | FFG 54 | 2.75 |

Authority: Executive Order 11964; 33 U.S.C. 1605.

Dated: November 20, 1984.

Approved:

John Lehman,

*Secretary of the Navy.*

[FR Doc. 84-32453 Filed 12-12-84; 8:45 am]

BILLING CODE 3810-AE-M

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## DEPARTMENT OF TRANSPORTATION

## Coast Guard

## 33 CFR Part 110

[CGD 7-83-29]

## Special Anchorage Area; Bahia de San Juan, PR

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is reclassifying Anchorage D in Bahia de San Juan as a Special Anchorage Area, for use by vessels less than 65 feet long. The anchorage area is currently being used by small pleasure craft. This change in classification relieves vessel