14 CFR Part 71

[Airspace Docket No. 83-AWA-28]

Alteration of VOR Federal Airway V-181-SD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Cancellation of final rule before effective date.

SUMMARY: This action cancels ASD 83-AWA-28 that was published in the Federal Register on November 22, 1985, and was to be effective March 13, 1986. The Yankton, SD, very high frequency omni-directional radio range distance measuring equipment (VOR/DME) has been relocated. However, due to engineering and technical problems associated with the new site location, Yankton VOR/DME has not received a satisfactory flight check for commissioning and acceptance into the National Airspace System (NAS). This action cancels ASD 83-AWA-28.

EFFECTIVE DATE: 0901 G.m.t, February 19, 1986.

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, DC 20591; telephone: (202) 426-8686.

SUPPLEMENTARY INFORMATION:

History

On November 22, 1985, the FAA published a final rule which amended Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to alter the description of V-181 located in the vicinity of Yankton, SD (50 FR 48178). The Yankton VOR/DME has been relocated on the Yankton Airport which is aproximately 1,350 feet north of its former location. Due to engineering and technical problems, Yankton VOR/DME has not received a satisfactory flight check. This action cancels ASD 83-AWA-28.

Reason For Cancellation

Yankton VOR/DME has not received a satisfactory flight check data report after numerous attempts. Therefore, ASD 83-AWA-28 is cancelled.

Cancellation of the Final Rule

The final rule issued in Airspace Docket No. 83-AWA-28 on November 12, 1985, which amended § 71.123, and which was published in the Federal Register on November 22, 1985 (50 FR 48178), and corrected January 2, 1986 (51 FR 6), is hereby cancelled.

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

Issued in Washington, D.C., on February 12, 1986.

Daniel J. Peterson,

Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 86-3533 Filed 2-18-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulation No. 4]

Federal Old-Age, Survivors, and Disability Insurance; Revised Medical Criteria for the Determination of Disability

Correction

In FR Doc. 85-28672 beginning on page 50068 in the issue of Friday, December 6, 1985, make the following corrections in Appendix 1 to Subpart P, Part 404:

1. On page 50092, in the first column, in paragraph 1, in the 11th line, insert "chest" after "of".

2. On page 50095, in the third column, in the first line, "Recent" should read "Recurrent".

3. On page 50098, in the second column, in the second line from the top of the page, insert "amenable" after "not".

4. On page 50099, in the second column, in the 26th line from the bottom of the column, "consideration" should read "considered".

5. On page 50103, in the second column, in the twelfth line above Table 1, "Tachycardia" should read "Tachypnea".

BILLING CODE 1505-01-M

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20 CFR Part 404

Federal Old-Age, Survivors, and Disability Insurance; Indexing for Widow(er)'s Benefits; Effect of Remarriage on Widow(er)'s Entitlement; Retroactivity of Widow(er)'s Benefits

Correction

In FR Doc. 86-2364, beginning on page 4480 in the issue of Wednesday, February 5, 1986, make the following correction: On page 4481, in the first column, in the seventh line of the third complete paragraph, the word "not" should read "now".

BILLING CODE 1505-01

Food and Drug Administration

21 CFR Part 73

[Docket No. 85C-0415]

Listing of Canthaxanthin as a Color Additive Exempt From Certification, and Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 20, 1985, for a regulation that provides for the safe use of canthaxanthin as a color additive in broiler chicken feed to enhance the yellow color of broiler chicken skin. This action responds to a petition filed by Hoffmann-LaRoche, Inc.

EFFECTIVE DATE: Effective date confirmed: December 20, 1985.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In a final rule published in the Federal Register of November 19, 1985 (50 FR 47532), FDA amended the color additive regulations (21 CFR 73.75) to provide for the safe use of canthaxanthin as a color additive in broiler chicken feed to enhance the yellow color of broiler chicken skin.

In the final rule, FDA gave interested persons until December 19, 1985, to file objections. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA has concluded that the final rule published in the Federal Register of November 19, 1985, for the safe use of canthaxanthin as a color additive in broiler chicken feed to enhance the yellow color of broiler chicken skin should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376))

and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the November 19, 1985, final rule. Accordingly, the amendments promulgated thereby became effective December 20, 1985.

Dated: February 11, 1986.

Adam J. Trujillo,

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 86-3496 Filed 2-18-86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 74

[Docket No. 84N-0083]

Confirmation of Effective Date for D&C Blue No. 6 as a Color Additive

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 29, 1985, for a regulation that removes the provision that bars the migration of D&C Blue No. 6 from sutures to the surrounding tissues under conditions of use. FDA took this action because the restriction is not necessary to assure the safety and suitability of the use of D&C Blue No. 6 in sutures.

EFFECTIVE DATE: Effective date confirmed: August 29, 1985.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a final rule published in the **Federal Register** of July 29, 1985 (50 FR 30697), FDA amended 21 CFR 74.3106 *D&C Blue No. 6* by removing paragraph (c)(3) from that regulation. That paragraph contained the provision that bars the migration of D&C Blue No. 6 from a suture to the surrounding tissues under conditions of use. FDA proposed to remove that paragraph in the **Federal Register** of July 25, 1984 (49 FR 29970). FDA removed the paragraph because the restriction is not necessary to assure the safety or suitability of the use of D&C Blue No. 6 in sutures. The restriction is also ambiguous when referring to absorbable sutures.

In the final rule, FDA gave interested persons until August 28, 1985, to file objections. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA has concluded that the final rule published in the **Federal Register** of July 29, 1985, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376)); and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the July 29, 1985, final rule. Accordingly, the amendments promulgated thereby became effective August 29, 1985.

Dated: February 11, 1986.

Adam J. Trujillo,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-3497 Filed 2-18-86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

Animal Drugs, Feed, and Related Products; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address for two new animal drug applications (NADA's) from Ivy-Gene Co., Inc., Washington, DC, to Ivy Laboratories, Inc., Overland Park, KS.

EFFECTIVE DATE: February 19, 1986.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, has filed supplemental NADA's informing FDA of a sponsor name and address change for NADA 110-315 (progesterone and estradiol benzoate) and NADA 135-906 (estradiol benzoate and testosterone propionate) from Ivy-Gene Co., Inc., 1731 Connecticut Avenue, NW., Washington, DC 20009. The NADA's are amended to reflect the change. There is no change in manufacturing site. The regulations in 21 CFR 510.600 are amended accordingly.

List of Subjects in 21 CFR 510

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

PART 510—NEW ANIMAL DRUGS

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 510 is amended as follows:

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. Section 510.600 is amended in paragraph (c)(1) by revising the entry for "Ivy-Gene Co., Inc.", and in paragraph (c)(2) by revising the entry for "021641", to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Ivy Laboratories, Inc., 8857 Bond Street, Overland Park, KS 66214	021641
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
021641	Ivy Laboratories, Inc., 8857 Bond Street, Overland Park, KS 66214.
* * * * *	

Dated: February 12, 1986.

Marvin A. Norcross,

Acting Associate Director for New Animal Drug Evaluation.

[FR Doc. 86-3500 Filed 2-18-86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Tylosin

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 a new animal drug

application (NADA) filed on behalf of Arkansas Micro Specialties, Inc., providing for manufacture of 5-, 10-, 20-, and 40-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens. The regulations are further amended to add the firm to the list of sponsors of approved applications.

EFFECTIVE DATE: February 19, 1986.

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: Arkansas Micro Specialties, Inc., P.O. Box 308, Hwy. 71 North, Lowell, AR 72745, is the sponsor of NADA 139–600 submitted on its behalf by Elanco Product Co. The NADA provides for manufacture of 5-, 10-, 20-, and 40-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1) (i) through (vi). The NADA is approved and the regulations are amended to reflect the approval. The regulations are further amended to add the firm to the list of sponsors of approved NADA's.

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, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR

Part 510

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

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, Parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. Part 510 is amended in § 510.600 by adding a new entry alphabetically in paragraph (c)(1) and numerically in paragraph (c)(2), to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Arkansas Micro Specialties Inc., P.O. Box 308, Highway 71 North, Lowell, AR 72745	047863
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
047863	Arkansas Micro Specialties Inc., P.O. Box 308, Highway 71 North, Lowell, AR 72745
* * * * *	

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343–351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

4. Part 558 is amended in § 558.625 by adding new paragraph(b)(86), To read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(86) To 047863: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

* * * * *

Dated: February 3, 1986

Gerald B. Guest,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 3498 Filed 2–18–86; 8:45 am]

BILLING CODE 4160-01-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 a new animal drug application (NADA) filed for Arkansas Micro Specialties, Inc. The NADA provides for the manufacture of premixes containing 5, 10, 20, or 40 grams per pound each of tylosin and sulfamethazine for use in making finished swine feeds.

EFFECTIVE DATE: February 19, 1986.

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: Arkansas Micro Specialites, Inc., Highway 71 North, P.O. Box 308, Lowell, AR 72745, is the sponsor of NADA 139–601 submitted on its behalf by Elanco Products Co. The NADA provides for the manufacture of premixes containing 5, 10, 20, or 40 grams per pound each of tylosin (as tylosin phosphate) and sulfamethazine intended for use in making finished swine feeds. The resulting feeds are for use in maintaining weight gains and feed efficiency in the presence of atrophic rhinitis, lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis, preventing swine dysentery (vibrionic), and controlling swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*). The NADA is approved and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human