

Greenville, MS, Mid Delta Regl, GPS RWY 18R, Orig
 Greenville, MS, Mid Delta Regl, GPS RWY 36L, Orig
 Greenville, MS, Mid Delta Regl, GPS RWY 36R, Orig
 Chapel Hill, NC, Horace Williams, GPS RWY 27, Orig
 Smithfield, NC, Johnston County, NDB RWY 3, Orig
 Smithfield, NC, Johnston County, ILS RWY 3, Orig
 Smithfield, NC, Johnston County, LOC/DME RWY 3, AMDT 1, CANCELLED
 Smithfield, NC, Johnston County, NDB OR GPS RWY 21, Amdt 6
 Crete, NE, Crete Muni, VOR/DME OR GPS RWY 17, Amdt 3
 Crete, NE, Crete Muni, VOR/DME RWY 35, Amdt 3
 Crete, NE, Crete Muni, NDB RWY 17, Amdt 2
 Crete, NE, Crete Muni, NDB RWY 35, Amdt 2
 Crete, NE, Crete Muni, GPS RWY 35, Orig
 Lumberton, NJ, Flying W, VOR OR GPS-A, Amdt 2
 Lumberton, NJ, Flying W, GPS RWY 1, Orig
 Lumberton, NJ, Flying W, GPS RWY 19, Orig
 Syracuse, NY, Syracuse Hancock Intl, VOR RWY 14, Amdt 22
 Syracuse, NY, Syracuse Hancock Intl, GPS RWY 10, Orig
 Syracuse, NY, Syracuse Hancock Intl, GPS RWY 14 Orig
 Syracuse, NY, Syracuse Hancock Intl, GPS RWY 28, Orig
 Syracuse, NY, Syracuse Hancock Intl, GPS RWY 32, Orig
 Wilmington, OH, Clinton Field, GPS RWY 21, Orig
 Tulsa, OK, Tulsa Intl, GPS RWY 26 Orig
 Tullahoma, TN, Tullahoma Regional Airport/WM Northern Field, VOR OR GPS-A, AMDT 3A, CANCELLED
 Tullahoma, TN, Tullahoma Regional Airport/WM Northern Field, VOR/DME-A, Orig
 Amarillo, TX, Amarillo Intl, GPS RWY 22, CANCELLED
 Fort Worth, TX, Bourland Field, GPS RWY 17, Orig
 Gillette, WY, Gillette-Campbell County, LOC/DME BC RWY 16, Amdt 3
 Manassas, VA, Manassas Regional/Harry P Davis Field, ILS RWY 16L, Amdt 4
 Manassas, VA, Manassas Regional/Harry P Davis Field, GPS RWY 16L, Orig
 Manassas, VA, Manassas Regional/Harry P Davis Field GPS RWY 34R, Orig
 Osceola, WI, L O Simenstad Muni, NDB RWY 28, Amdt 10
 Osceola, WI, L O Simenstad Muni, GPS RWY 28, Orig
 Elkins, WV, Elkins-Randolph Co-Jennings Randolph Field, VOR/DME-B Amdt 3A, CANCELLED
 Elkins, WV, Elkins-Randolph Co-Jennings Randolph Fld, GPS RWY 5, Orig
 Elkins, WV, Elkins-Randolph Co-Jennings Randolph Fld, NDB-A, Orig
 Pineville, WV, Kee Field, GPS RWY 25, Orig
 [FR Doc. 97-29727 Filed 11-10-97; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 29053; Amdt. No. 1832]

RIN 2120-AA65

Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located; or
3. The Flight Inspection Area Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S.

Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS-420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4, and 8260-5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

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 “significant regulatory action” under Executive Order 12866; (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. For the same reason, the FAA certifies that this amendment 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 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on October 31, 1997.

Richard O. Gordon,

Deputy Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach

Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective Upon Publication*

FDC date	State	City	Airport	FDC No.	SIAP
10/16/97	IL	CHICAGO/AURORA	AURORA MUNI	7/6782	VOR OR GPS RWY 36, AMDT 1A...
10/20/97	MS	PASCAGOULA	TRENT LOTT INTL	7/6828	ILS RWY 17, ORIG-1A...
10/20/97	MS	PASCAGOULA	TRENT LOTT INTL	7/6829	GPS RWY 17, ORIG...
10/20/97	MS	PASCAGOULA	TRENT LOTT INTL	7/6830	VOR OR GPS-A, ORIG...
10/21/97	KS	COFFEYVILLE	COFFEYVILLE MUNI	7/6854	VOR/DME OR GPS-A, AMDT 6A...
10/22/97	GA	JEFFERSON	JACKSON COUNTY	7/6883	NDB RWY 34, ORIG...
10/22/97	MN	MINNEAPOLIS	CRYSTAL	7/6864	GPS RWY 13L, ORIG...
10/22/97	MN	MINNEAPOLIS	CRYSTAL	7/6865	VOR OR GPS-A, AMDT 9B...
10/22/97	MN	MINNEAPOLIS	FLYING CLOUD	7/6860	VOR OR GPS RWY 36, AMDT 11A...
10/22/97	MN	MINN3APOLIS	FLYING CLOUD	7/6861	VOR OR GPS RWY 9R, AMDT 7A...
10/22/97	MN	MINNEAPOLIS	FLYING CLOUD	7/6863	ILS RWY 9R, AMDT 1A...
10/22/97	MN	MORRIS	MORRIS MUNI	7/6857	VOR OR GPS RWY 32, AMDT 4A...
10/23/97	TX	LUBBOCK	LUBBOCK INTL	7/6908	VOR/DME OR TACAN RWY 26, AMDT 10...
10/28/97	LA	ALEXANDRIA	ALEXANDRIA INTL	7/6989	VOR OR GPS RWY 32, ORIG-A...
10/28/97	LA	ALEXANDRIA	ALEXANDRIA INTL	7/6990	VOR OR GPS RWY 14, ORIG-B...
10/28/97	LA	ALEXANDRIA	ALEXANDRIA INTL	7/6991	GPS RWY 18, ORIG-A...
10/28/97	MI	GRAND RAPIDS	KENT COUNTY INTL	7/6972	RADAR-1, AMDT 10...
10/29/97	LA	ALEXANDRIA	ALEXANDRIA INTL	7/7006	ILS/DME RWY 14, AMDT 1...

Jefferson

JACKSON COUNTY
Georgia
NDB RWY 34, ORIG...
FDC Date: 10/22/97

FDC 7/FDC 7/6883 /19A/ FI/P JACKSON COUNTY, JEFFERSON, GA. NDB RWY 34, ORIG...TERMINAL ROUTE WOMAC INT TO COMMERCE NDB MIN ALT 3700. THIS IS NDB RWY 34 ORIG-A.

Chicago/Aurora

AURORA MUNI
Illinois
VOR OR GPS RWY 36, AMDT 1A...

FDC Date: 10/16/97

FDC 7/6782 /ARR/FI/P AURORA MUNI, CHICAGO/AURORA, IL. VOR OR GPS RWY 36, AMDT 1A...CHANGE NOTE TO READ... WHEN CONTROL TOWER CLOSED USE DUPAGE ALTIMETER SETTING. CHANGE ALTERNATE MINIMUMS TO READ... STANDARD, EXCEPT NA WHEN CONTROL TOWER CLOSED. THIS IS VOR OR GPS RWY 36, AMDT 1B.

Coffeyville

COFFEYVILLE MUNI
Kansas
VOR/DME OR GPS-A, ADMT 6A...

FDC Date: 10/21/97

FDC 7/6854 /CFV/ FI/P COFFEYVILLE MUNI, COFFEYVILLE, KS. VOR/DME OR GPS-A, AMDT 6A...CIRCLING MDA 1200/ HAA 466 CAT A. THIS IS VOR/DME OR GPS-A, AMDT 6B.

Alexandria

ALEXANDRIA INTL
Louisiana
VOR OR GPS RWY 32, ORIG-A...
FDC Date: 10/28/97

FDC 7/6989 /AEX/ FI/P ALEXANDRIA INTL, ALEXANDRIA, LA. VOR OR GPS RWY 32, ORIG-A...CIRCLING CAT A MDA 520/

HAA CAT A 431. CAT B/C HAA 451. CAT D HAA 551. NOTE...RADAR REQUIRED. THIS IS VOR OR GPS RWY 32, ORIG-B.

Alexandria

ALEXANDRIA INTL
Louisiana
VOR OR GPS RWY 14, ORIG-B...
FDC Date: 10/28/97

FDC 7/6990 /AEX/ FI/P ALEXANDRIA INTL, ALEXANDRIA, LA. VOR OR GPS RWY 14, ORIG-B...CIRCLING CAT A MDA 520/HAA CAT A 431. CAT B/C HAA 451, CAT D HAA 551. NOTE...WHEN R-3801 B ACTIVE, RADAR REQUIRED. NOTE...FOR INOPERATIVE ALSF INCREASE S-14 CAT D VISIBILITY TO 1¼. THIS IS VOR OR GPS RWY 14, ORIG-C.

Alexandria

ALEXANDRIA INTL
Louisiana
VOR OR GPS RWY 18, ORIG-A...
FDC Date: 10/28/97

FDC 7/6991 /AEX/ FI/P ALEXANDRIA INTL, ALEXANDRIA, LA GPS RWY 18, ORIG-A...NOTE... WHEN R-3801 A OR B ACTIVE, RADAR REQUIRED. THIS IS GPS RWY 18, ORIG-B.

Alexandria

ALEXANDRIA INTL
Louisiana
ILS/DME RWY 14, AMDT 1...
FDC Date: 10/29/97

FDC 7/7006 /AEX/ FI/P ALEXANDRIA INTL, ALEXANDRIA, LA. ILS/DME RWY 14, AMDT 1...CIRCLING CAT A MDA 520/HAT CAT A 431. CAT B/C/ HAT 451. CAT D HAT 551. NOTE... WHEN R-3801 B ACTIVE, RADAR REQUIRED. THIS IS ILS/DME RWY 14, AMDT 1A.

Grand Rapids

KENT COUNTY INTL
MICHIGAN
RADAR-1, AMDT 10...
FDC Date: 10/28/97

FDC 7/6972/GRR/ FI/P KENT COUNTY INTL, GRAND RAPIDS, MI. RADAR-1, AMDT 10...S-26R MDA 1160/HAT 373 ALL CATS. THIS IS RADAR-1, AMDT 10A.

Morris

MORRIS MUNI
Minnesota
VOR OR GPS RWY 32, AMDT 4A...
FDC Date: 10/28/97

FDC 7/6857 /MOX/ FI/P MORRIS MUNI, MORRIS, MN. VOR OR GPS RWY 32, AMDT 4A...CHANGE DME MNMS...S-32... MDA 1500/HAT 370, ALL CATS. THIS IS VOR OR GPS RWY 32, AMDT 4B.

Minneapolis

FLYING CLOUD
Minnesota
VOR OR GPS RWY 36, AMDT 11A...
FDC Date: 10/22/97

FDC 7/6860 /FCM/ FI/P FLYING CLOUD, MINNEAPOLIS, MN. VOR OR GPS RWY 36, AMDT 11A...DELETE NOTE...WHEN CONTROL TOWER CLOSED, USE MINNEAPOLIS ST. PAUL INTL ALTIMETER SETTING AND INCREASE ALL MDA'S 40 FEET DELETE PROFILE NOTE...ASTERISK

1460 WHEN USING MINNEAPOLIS ALTIMETER SETTING. ALTERNATE MNMS STANDARD. ADD...CHART ASOS. THIS IS VOR OR GPS RWY 36, AMDT 11B.

Minneapolis

FLYING CLOUD
Minnesota
VOR OR GPS RWY 9R, AMDT 71A...
FDC Date: 10/22/97

FDC 7/6861 /FCM/ FI/P FLYING CLOUD, MINNEAPOLIS, MN. VOR OR GPS RWY 9R, AMDT 7A...DELETE NOTE...WHEN CONTROL TOWER CLOSED, USE MINNEAPOLIS ST. PAUL INTL ALTIMETER SETTING AND INCREASE ALL MDA'S 40 FEET AND INCREASE CAT C S-9R DME VIS TO ¾ MILE. DELETE PROFILE NOTE... ASTERISK 1400 WHEN USING MINNEAPOLIS ALTIMETER SETTING. ALTERNATE MNMS STANDARD. ADD... CHART ASOS. THIS IS VOR OR GPS RWY 9R, AMDT 7B.

Minneapolis

FLYING CLOUD
Minnesota
ILS RWY 9R, AMDT 1A...
FDC Date: 10/22/97

FDC 7/6863/FCM/FI/P FLYING CLOUD, MINNEAPOLIS, MN. ILS RWY 9R, AMDT 1A...DELETE NOTE... WHEN CONTROL TOWER CLOSED, USE MINNEAPOLIS ST. PAUL INTL ALTIMETER SETTING AND INCREASE ALL DH/MDA'S 40 FEET, AND INCREASE CAT C S-LOC 9R DME VIS TO ¾ MILE. DELETE PROFILE NOTE...ASTERISK 1380 WHEN USING MINNEAPOLIS ALTIMETER SETTING. ALTERNATE MNMS STANDARD. ADD...CHART ASOS. THIS IS ILS RWY 9R, AMDT 1B.

Minneapolis

CRYSTAL
Minnesota
GPS RWY 13L, ORIG...
FDC Date: 10/22/97

FDC 7/6864 /MIC/ FI/P CRYSTAL, MINNEAPOLIS, MN. GPS RWY 13L, ORIG...DELETE...MINNEAPOLIS ALTIMETER SETTING MNMS. DELETE NOTE... WHEN CONTROL TOWER CLOSED, USE MINNEAPOLIS ALTIMETER SETTING. ADD... CHART ASOS. THIS IS GPS RWY 13L, AMDT ORIG-A.

Minneapolis

CRYSTAL
Minnesota
VOR OR GPS-A, AMDT 9B...
FDC Date: 10/22/97

FDC 7/6865 /MIC/FI/P CRYSTAL, MINNEAPOLIS, MN. VOR OR GPS-A, AMDT 9B...DELETE... MINNEAPOLIS ALTIMETER SETTING MNMS. DELETE NOTE... WHEN CONTROL TOWER CLOSED, USE MINNEAPOLIS ALTIMETER SETTING. ALTERNATE

MNMS STANDARD. ADD... CHART ASOS. THIS IS VOR OR GPS-A, AMDT 9C.

Pascagoula

TRENT LOTT INTL
Mississippi
ILS RWY 17, ORIG-A
FDC Date: 10/20/97...

FDC 7/6828 /PQL/ FI/P TRENT LOTT INTL, PASCAGOULA, MS. ILS RWY 17, ORIG-A...DELETE NOTE... OBTAIN LOCAL ALTIMETER SETTING ON CTAF, WHEN NOT RECEIVED USE MOBILE ALTIMETER SETTING. MOBILE ALTIMETER SETTING MINIMUMS FOR INOPERATIVE MALSR, INCREASE S-ILS RWY 17 VISIBILITY TO 1 ALL CATS. DELETE... MOBILE ALTIMETER SETTING MINIMUMS. THIS IS ILS RWY 17, ORIG-B.

Pascagoula

TRENT LOTT INTL
Mississippi
GPS RWY 17, ORIG...
FDC Date: 10/20/97

FDC 7/6829 /PQL/ FI/P TRENT LOTT INTL, PASCAGOULA, MS. GPS RWY 17, ORIG...DELETE MOBILE, AL. ALTIMETER MINIMUMS. DELETE NOTE... OBTAIN LOCAL ALTIMETER SETTING ON CTAF, WHEN NOT RECEIVED USE MOBILE ALTIMETER SETTING. THIS IS GPS RWY 17, ORIG-A.

Pascagoula

TRENT LOTT INTL
Mississippi
VOR OR GPS-A, ORIG...
FDC Date: 10/20/97

FDC 7/6830 /PQL/FI/P TRENT LOTT INTL, PASCAGOULA, MS. VOR OR GPS-A, ORIG...DELETE MOBILE ALTIMETER SETTING MINIMUMS. DELETE NOTE... OBTAIN LOCAL ALTIMETER SETTING ON CTAF, IF NOT RECEIVED USE MOBILE ALTIMETER SETTING. ALTERNATE MINIMUMS... CATS A/B/C STANDARD, CAT D 800-2¼. THIS IS VOR OR GPS-A, ORIG-A.

Lubbock

LUBBOCK INTL
Texas
VOR/DME OR TACAN RWY 26, AMDT 10...
FDC Date: 10/23/97

FDC 7/6908/LBB/FI/P LUBBOCK INTL, LUBBOCK, TX. VOR/DME OR TACAN RWY 26, AMDT 10...S-26 VSBY CAT A/B 1.CHANGE INOPERATIVE TABLE NOTE TO READ... INOPERATIVE TABLE DOES

NOT APPLY. THIS IS VOR/DME OR TACAN RWY 26, AMDT 10A.

[FR Doc. 97-29726 Filed 11-10-97; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for oral use of chlortetracycline hydrochloride soluble powder in the drinking water of swine for control and treatment of certain diseases caused by pathogens susceptible to chlortetracycline and chickens and turkeys for control of certain diseases caused by pathogens susceptible to chlortetracycline.

EFFECTIVE DATE: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-236 that provides for oral use of chlortetracycline hydrochloride soluble powder in animal drinking water as follows: (1) Swine: Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Haemophilus* spp.) and *Klebsiella* spp.; (2) Chickens: Control of infectious synovitis caused by *Mycoplasma synoviae*, and chronic respiratory disease (CRD) and air-sac infections caused by *M. gallisepticum* and *E. coli*; and (3) Turkeys: Control of infectious synovitis caused by *M. synoviae* and complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

Approval of Phoenix Scientific Inc.'s ANADA 200-236 chlortetracycline hydrochloride soluble powder is as a generic copy of ADM Animal Health &

Nutrition Div.'s NADA 65-256 Chlortet™-Soluble-O chlortetracycline hydrochloride soluble powder. ANADA 200-236 is approved as of September 24, 1997, and the regulations are amended in 21 CFR 520.445b(b) 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 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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 520

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, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder* (*chlortetracycline hydrochloride* or *chlortetracycline bisulfite*) is amended in paragraph (b) by removing "No. 017519" and adding in its place "Nos. 017519 and 059130."

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-29650 Filed 11-10-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Oral Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Pharmacia & Upjohn Co. The supplemental ANADA provides for a shorter withdrawal period following use of neomycin sulfate oral solution in the drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis.

EFFECTIVE DATE: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed supplemental ANADA 200-113 that provides for a shorter withdrawal period following use of neomycin sulfate oral solution in the drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

Approval of supplemental ANADA 200-113 is as a generic copy of the sponsor's approved supplemental NADA 11-315. The supplemental ANADA is approved as of February 7, 1997, and the regulations are amended in § 520.1485(d)(3) (21 CFR 520.1485(d)(3)) to reflect the approval.

The previously approved supplement to NADA 11-315 included data to support revised tolerances for residues of neomycin in the edible tissues of cattle, swine, sheep, and goats. Based on evaluation of the data as provided in the "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals Guidelines," tolerances of 1.2 parts per million (ppm) in muscle, 3.6 ppm in liver, and 7.2 ppm in kidney and fat, and withdrawal times of 1 day for cattle, 2 days for sheep, and 3 days for swine and goats were established. The revised withdrawal times were established in 21