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

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC, on April 12, 1991.

Thomas C. Accardi,

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 G.m.t. on the dates specified, as follows:

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

PART 97—[AMENDED]

Authority: 49 U.S.C. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 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 July 25, 1991**

Zanesville, OH—Zanesville Muni, VOR/DME RWY 4, Amdt. 1, Cancelled
Zanesville, OH—Zanesville Muni, VOR RWY 4, Amdt. 6
Zanesville, OH—Zanesville Muni, VOR RWY 22, Amdt. 3
Zanesville, OH—Zanesville Muni, NDB-A, Amdt. 1

*** * * Effective June 27, 1991**

Beloit, WI—Beloit, VOR-A, Amdt. 5

*** * * Effective May 30, 1991**

Colorado Springs, CO—City of Colorado Springs Muni, NDB RWY 35, Amdt. 25
Colorado Springs, CO—City of Colorado Springs Muni, ILS RWY 17, Amdt. 4
Ft. Myers, FL—Page Field, VOR RWY 5, Amdt. 8, Cancelled
Ft. Myers, FL—Page Field, VOR RWY 13, Amdt. 7, Cancelled
New Smyrna Beach, FL—Massey Ranch Airpark, NDB RWY 18, Orig.
New Smyrna Beach, FL—NDB RWY 29, Amdt. 1
Ocean City, MD—Ocean City Muni, LOC RWY 14, Orig.
Motley, MN—Morey Fish House, VOR RWY 9, Amdt. 1, Cancelled
Dexter, MO—Dexter Muni, NDB RWY 36, Orig.
Osage Beach, MO—Linn Creek-Grand Glaize Meml, VOR RWY 32, Amdt. 4
Belmar/Farmingdale, NJ—Allaire, LOC/DME RWY 14, Orig.
Rock Hill, SC—Rock Hill Municipal/Bryant Field, VOR-A, Amdt. 8
Rock Hill, SC—Rock Hill Municipal/Bryant Field, VOR/DME-B, Amdt. 3
Big Spring, TX—Big Spring MC Mahon-Wrinkle, VOR/DME RWY 17, Amdt. 7
Big Spring, TX—Big Spring MC Mahon-Wrinkle, VOR/DME RWY 35, Amdt. 7
Tacoma, WA—Tacoma Narrows, ILS RWY 17, Amdt. 7
Tacoma, WA—Tacoma Narrows, NDB RWY 35, Amdt. 4

*** * * Effective May 2, 1991**

Keene, NH—Dillant-Hopskins, LOC RWY 2, Amdt. 1
Charlotte, NC—Charlotte/Douglas Intl, ILS RWY 18L, Amdt. 1

*** * * Effective April 9, 1991**

Orangeburg, SC—Orangeburg Muni, VOR RWY 5, Amdt. 3
Orangeburg, SC—Orangeburg Muni, NDB RWY 5, Amdt. 3

*** * * Effective April 5, 1991**

Birmingham, AL—Birmingham, ILS RWY 5, Amdt. 39

*** * * Effective April 4, 1991**

Lawrenceville, GA—Gwinnett County-Briscoe Field, NDB RWY 25, Amdt. 1
Lawrenceville, GA—Gwinnett County-Briscoe Field, VOR/DME RWY 7, Amdt. 1

*** * * Effective March 29, 1990**

Denver, CO—Front Range, NDB RWY 26, Admt. 1

[FR Doc. 91-9922 Filed 4-25-91; 8:45 am]

BILLING CODE 4910-13-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1211

Extraterrestrial Exposure

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: NASA is removing 14 CFR part 1211 since it has served its purpose and is no longer in keeping with current policy.

EFFECTIVE DATE: April 26, 1991.

ADDRESSES: Office of Space Science and Applications, Code S, NASA Headquarters, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Kathryn S. Schmoll, 202-453-1410.

List of Subjects in 14 CFR Part 1211

Extraterrestrial exposure, Environmental protection, Security measures, Space transportation and exploration.

PART 1211—[REMOVED]

14 CFR part 1211 (consisting of §§ 1211.100 through 1211.108) is hereby removed and reserved.

Richard H. Truly,

Administrator.

[FR Doc. 91-9904 Filed 4-25-91; 8:45 am]

BILLING CODE 7510-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 148

[T.D. No. 91-35]

Registration of Personal Effects To Be Taken Abroad

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: The U.S. Customs Service is amending its regulations to permit distribution of blank copies of the Customs Registration Form used by travelers to register foreign-made articles which they are taking with them when they travel outside the United States. Prior to this amendment, travelers could not obtain blank copies of this form. Because all merchandise of foreign origin is subject to a Customs duty, travelers should register foreign-made goods with Customs before departing the United States. This will facilitate identification of the goods upon the traveler's return and exempt them from duty assessment. This amendment is being made to help eliminate delays and frustrations which are sometimes encountered when many travelers complete the form at an airport just prior to departure.

EFFECTIVE DATE: April 26, 1991.

FOR FURTHER INFORMATION CONTACT: Linda Walfish, Office of Inspection and Control, (202) 566-9425.

SUPPLEMENTARY INFORMATION:

Background

All merchandise of foreign origin imported into the United States is subject to a customs duty unless it has been specifically exempted from this duty. Under § 148.1(a), Customs Regulations (19 CFR 148.1(a)), any person, except a nonresident seaman, airman, or person engaged in similar employment, who intends to take effects

of foreign origin abroad may register such articles before departure from the United States in order to facilitate their identification on return to the United States. Only articles of foreign origin having serial numbers or other distinctive, permanently affixed unique markings can be registered.

Under § 148.1(b), travelers desiring to register articles of foreign origin must present the articles to a Customs officer and, at that time, complete a Customs Form 4457. After the Customs officer has examined the articles and verified their description, he will sign the form and return it to the applicant for presentation on return of the articles. A Customs Form 4455, "Certificate of Registration," could be required in instances when Customs Form 4457 will not adequately serve the purpose of registration.

In 1982, when Customs last revised its regulations governing the use of Customs Form 4457, there was concern that fraudulent use of the form could seriously jeopardize revenue collection. That was the rationale for the requirement that the traveler present the articles to be registered before being issued the form.

Customs has reevaluated that position, and has determined that Customs Form 4457 may now be made available to travelers upon their request in advance of their arrival at the Customs office. By permitting travelers to fill out Customs Form 4457 prior to their arrival at a Customs office, delays and frustrations encountered while travelers attempt to fill out the registration forms at the Customs offices will be eliminated, or at least, greatly reduced. The good will generated and savings in time and personnel requirements will significantly outweigh any potential for fraudulent use of the form. Travelers will still have to present both the properly prepared form and the articles being registered to the Customs officer in order to have the form validated. The form will have to be signed in the presence of the Customs officer. All other existing requirements regarding the registration of foreign made articles will remain unaffected by this amendment.

Travelers will be able to obtain a blank Customs Form 4457 and instructions for preparing the form by visiting, telephoning, or writing to any Customs office and requesting that a copy of the form be given or sent to them. It is also anticipated that travel agencies will obtain blank forms and instruction sets for their clients.

The Customs Service believes that this change will benefit both the traveling public and Customs by eliminating an unnecessary delay in the departure process for travelers, speeding processing for both travelers and Customs officers, and reducing the number of officers needed in the registration area.

Inapplicability of Notice and Delayed Effective Date

Because this amendment relaxes an administrative requirement, pursuant to section 553(b)(B) of the Administrative Procedure Act, no notice of proposed rulemaking or public procedure is necessary. For the same reason, a delayed effective date is inappropriate.

Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), it is certified that the amendment will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified in E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Drafting Information

The principal author of this document was Peter T. Lynch, Regulations and Disclosure Law Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 148

Customs duties and inspection, Imports, Personal declarations and exemptions.

Part 148, Customs Regulations (19 CFR part 148) is amended as set forth below:

PART 148—PERSONAL DECLARATIONS AND EXEMPTIONS

1. The general authority citation for part 148, Customs Regulations (19 CFR 148), continues to read as follows:

Authority: 19 U.S.C. 66, 1496, 1624. The provisions of this part, except for subpart C, are also issued under General Note 8, Harmonized Tariff Schedule of the United States, 19 U.S.C. 1202;

* * * * *

2. Section 148.1 is amended by revising paragraph (b) to read as follows:

§ 148.1 Registration of effects to be taken abroad.

* * * * *

(b) *Procedures for registration.* Applicants for registration of articles of foreign origin shall present the articles, together with a completed, but unsigned, Customs Form 4457, which may be obtained in advance of departure, to a Customs officer. After the Customs officer has examined the articles and verified their description, he shall have the applicant sign the form. The Customs officer shall then sign the form and return it to the applicant for presentation on return of the articles. Customs form 4455 may be required in any case in which Customs form 4457 will not adequately serve the purpose of registration.

* * * * *

Approved: March 29, 1991.

Carol Hallett,

Commissioner of Customs.

John P. Simpson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 91-9827 Filed 4-25-91; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

[Regulations No. 16]

RIN 0960-AC51

Supplemental Security Income for the Aged, Blind, and Disabled; Interim Assistance Provisions

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: These final regulations reflect changes in interim assistance policy resulting from section 9110 of the Omnibus Budget Reconciliation Act of 1987, Public Law 100-203, which amended section 1631(g) of the Social Security Act (the Act). This provision extends interim assistance reimbursement (IAR) to assistance provided by a State to an individual for a month or months the individual's supplemental security income (SSI) benefits and/or federally administered State supplementary payments are suspended or terminated, if it is determined subsequently that the individual was eligible for such benefits or payments for such months. These final regulations also clarify our policy to provide that a State may be reimbursed only on a prorated basis for assistance provided to an individual for the initial month of eligibility for SSI benefits and for the month his or her SSI benefits are reinstated after a period of

suspension or termination. The effects of these final regulations are to increase State IAR in cases of reinstatement of SSI after suspension and to decrease State IAR in those cases of first eligibility where we prorate the IAR.

EFFECTIVE DATE: April 26, 1991.

FOR FURTHER INFORMATION CONTACT: Duane Heaton, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (301) 965–8470.

SUPPLEMENTARY INFORMATION:

Provisions of the Regulations

Section 1631(g) of the Act, before amendment, authorized the Social Security Administration (SSA) to make the first payment of SSI benefits and/or State supplementary payments (including retroactive payments, if any) due an individual to a State or political subdivision as reimbursement for interim assistance furnished on behalf of the individual by the State if: The State had entered into an IAR agreement with SSA; the individual had signed an IAR authorization form approved by SSA and the State permitting such payment of benefits to the State; and the individual had received interim assistance during the period his or her SSI application was pending. Under these final regulations SSA, upon written authorization by an individual, will reimburse the State from the retroactive SSI benefits and/or State supplementary payments due the individual for interim assistance provided to the individual while the individual's SSI benefits and/or State supplementary payments were suspended or terminated, if it is determined subsequently that he or she was eligible for such benefits and/or payments for such month or months (the posteligibility period). Reimbursement will include only amounts payable for months for which an authorization is effective. A separate IAR authorization for each posteligibility period is required for this reimbursement to enable the SSA district or branch office to distinguish the posteligibility authorization from a prior authorization relating to the individual's initial claim.

In order to avoid confusion about what constitutes interim assistance for months when the SSI benefit is subject to proration, we have modified the definition of interim assistance in § 416.1902. The change makes it clear that interim assistance means assistance furnished by the State beginning with the day an individual applies and is eligible for SSI benefits, or with the day for which SSI eligibility is reinstated after a period of suspension or termination, rather than with the month for which his or her eligibility begins. Consequently, under this definition, the assistance amount payable by a State for a full month will be prorated to determine the amount of IAR in the same fashion as is the SSI benefit under § 416.421.

This clarification in our interim assistance policy will eliminate the ambiguity under which some States have not prorated the assistance amount payable for a full month for the month of initial eligibility or reeligibility for SSI benefits. While we recognize that this clarification may result in less reimbursement to those States that have not prorated interim assistance, we believe the legislative history of IAR reasonably indicates that Congress intended for States participating in IAR to be reimbursed only for assistance paid for periods that overlap the periods for which the SSI benefits subsequently are paid. (See 120 Cong. Rec. 20967–68 (1974).) Thus, our definition of interim assistance would require all participating IAR States, in determining their IAR, to prorate the assistance amount payable for a full month for the initial month of eligibility for SSI benefits as well as the month for which eligibility is reinstated after periods of suspension or termination. SSA follows the proration rules in § 416.421 to prorate SSI benefits and the States will prorate for reimbursement purposes in the same manner. Thus, under our policy, for the initial month of eligibility or reeligibility, States may be reimbursed for assistance provided individuals only for those days in the month for which it is determined subsequently that the individuals are eligible for SSI benefits.

Public Comments

These final regulations were published as a notice of proposed rulemaking (NPRM) on February 8, 1990 (55 FR 4438). The NPRM provided for a 60-day comment period. We received one comment on the NPRM from a city human resource administration. The following summarizes and responds to the comment.

Comment: The statute states that interim assistance begins with the month of application or with the first month for which terminated or suspended SSI benefits were reinstated. Thus, to prorate interim assistance by regulation conflicts with the statute.

Response: We do not agree that to prorate interim assistance conflicts with the statute. The legislative history of the interim assistance provision reveals that Congress intended States to reimburse themselves only for assistance payments they furnish for the period that overlaps the period for which SSI benefits are payable. Senator Long, then Chairman of the Senate Finance Committee, in his statements on the floor, explained that the interim assistance provisions would authorize the withholding from the initial SSI check, upon authorization by the individual, of "an amount sufficient to reimburse the State for any interim payments it may have made to him in lieu of SSI benefits for which he was eligible but which had not yet been processed." (120 Cong. Rec. 20,967–68 (1974)).

As a result of proration, SSI benefits for an initial month of eligibility or a month after a month or more of ineligibility are to be paid at a reduced rate proportionate to the number of days in the month that the individual is eligible for benefits. Thus, it would appear that properly reimbursable interim assistance should also be prorated since, consistent with legislative intent, such amount would appear to be the only assistance furnished by the State that would have been paid "in lieu of SSI benefits for which * * * (the individual) was eligible."

Accordingly, we are declining to withdraw the rules based on the commenter's belief that they conflict with the statute. We are adopting the rules as proposed.

Regulatory Procedures

Executive Order No. 12291

The Secretary has determined that this is not a major rule under the terms of Executive Order 12291 because no additional program costs are contemplated, administrative costs are less than $1 million, and the threshold criteria for a major rule are not otherwise met. Therefore, a regulatory impact analysis is not required.

Paperwork Reduction Act of 1980

These final regulations impose no new reporting or recordkeeping requirements subject to Office of Management and Budget clearance.

Regulatory Flexibility Act

We certify that these final regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals and States. Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 93.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 416

Administrative Practice and Procedure, Aged, Blind, Disability benefits; Public assistance programs, Supplemental Security Income.

Dated: December 5, 1990.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: March 27, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set out in the preamble, part 416 of Chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

PART 416—[AMENDED]

1. The authority citation for subpart S of part 416 continues to read as follows:

Authority: Secs. 1102 and 1631 of the Social Security Act; 42 U.S.C. 1302 and 1383.

2. Section 416.1901 is amended by revising paragraph (a) to read as follows:

§ 416.1901 Scope of subpart S.

(a) *General.* This subpart explains that we may withhold your SSI benefit and/or State supplementary payments and send them to the State (or a political subdivision of the State) as repayment for interim assistance it gave you while your application for SSI was pending, or while your SSI benefits were suspended or terminated if you are subsequently found to have been eligible for such benefits. Before we will do this, the State must have entered into an interim assistance agreement with us authorizing such reimbursement, and you must have given written authorization for us to repay the State (or a political subdivision of the State).

* * * * *

3. Section 416.1902 is amended by revising the definitions of "Authorization", "Interim assistance", and "SSI benefit payment" to read as follows:

§ 416.1902 Definitions.

* * * * *

Authorization means your written permission, in a form legally acceptable to us and to the State from which you received interim assistance, for use to withhold the appropriate SSI benefit payment and send it to the State.

Interim assistance means assistance the State gives you, including payments made on your behalf to providers of goods or services, to meet basic needs, beginning with the day of the month you apply for SSI benefits and are eligible for them, and ending with, and including, the month your SSI benefit payments begin, or assistance the State gives you beginning with the day for which your eligibility for SSI benefits is reinstated after a period of suspension or termination and ending with, and including, the month the Secretary makes the first payment of benefits following the suspension or termination if it is determined subsequently that you were eligible for benefits during that period. It does not include assistance the State gives to or for any other person. If the State has prepared and cannot stop delivery of its last assistance payment to you when it receives your SSI benefit payment from us, that assistance payment is included as interim assistance to be reimbursed. Interim assistance does not include assistance payments financed wholly or partly with Federal funds.

SSI benefit payment means your Federal benefit and any State supplementary payment made by us to you on behalf of a State (see subpart T of this part) which is due you at the time we make the first payment of benefits or when your benefits are reinstated after suspension or termination. Advance payment, as defined in § 416.520, payment based upon presumptive disability or presumptive blindness, as defined in § 416.931, or certain payments made under the administrative immediate payment procedure, are not considered SSI benefit payments for interim assistance purposes.

* * * * *

4. Section 416.1906 is amended by revising paragraph (a) to read as follows:

§ 416.1906 When your authorization is in effect.

* * * * *

(a) We make the first SSI benefit payment on your initial application for benefits or, in the case of an authorization effective for a period of suspense or termination, until the initial payment following the termination or suspension of your benefits.

* * * * *

[FR Doc. 91-9951 Filed 4-25-91; 8:45 am]

BILLING CODE 4190-29-M

Food and Drug Administration

21 CFR Parts 510 and 555

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from M.K. Laboratories, Inc. (formerly McKesson Laboratories, Inc.), to John J. Ferrante.

EFFECTIVE DATE: April 26, 1991.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-1414.

SUPPLEMENTARY INFORMATION: John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611, informed FDA of acquiring NADA 65-137 from M.K. Laboratories, Inc. (formerly McKesson Laboratories, Inc.), Bridgeport, CT 06602, through their trustee, Thomas M. Germain, 410 Asylum St., Hartford, CT 06103. The NADA, originally approved November 19, 1968, provides for use of 100- and 250-milligram chloramphenicol (Amphicol-V) capsules to treat dogs. The regulations are amended in 21 CFR 510.600(c) by removing McKesson Laboratories, Inc., because the firm is no longer sponsor of any approved NADA's; by adding John J. Ferrante as a new sponsor; and in 21 CFR 555.110b(c)(2)(ii) by removing "000022" and adding "058034" to reflect the new sponsor.

List of Subjects

21 CFR Part 510

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

21 CFR Part 555

Animal drugs, Antibiotics.

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 Parts 510 and 555 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. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry "McKesson Laboratories, Inc.," and by alphabetically adding the entry

"John J. Ferrante," and in the table in paragraph (c)(2) by removing the entry "000022" and by numerically adding entry "058034" 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
* * * * *	
John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611	058034
* * * * *	

(2) * * *

Firm name and address	Drug labeler code
* * * * *	
John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611	058034
* * * * *	

PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

3. The authority citation for 21 CFR part 555 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 555.110b [Amended]

4. Section 555.110b *Chloramphenicol capsules* is amended in paragraph (c)(2)(ii) by removing "000022" and inserting in its place "058034".

Dated: January 25, 1991.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation Center for Veterinary Medicine.

[FR Doc. 91-9915 Filed 4-25-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

[Docket No. 86N-0451]

New Animal Drugs for Use in Animal Feeds; Removal of Portions of Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions of § 558.20 *Drugs used in medicated feeds in use before January 1, 1958, which are not otherwise listed; interim listing* (21 CFR 558.20) pertaining to: (1) Butynorate (dibutyltin dilaurate), which is being codified to reflect a previously approved new animal drug application (NADA); (2) nitarsone, which has previously been codified and whose status is unchanged; and (3) neomycin, phenothiazine, and piperazine, which are not the subject of approved NADA's providing for their use as sole drug ingredients in Type A medicated articles or in Type B or C medicated feeds. Additionally, FDA is codifying certain uses of arsanilic acid to reflect a previously approved NADA, amending § 558.4 to reflect the removal of neomycin, phenothiazine and piperazine, and editorially revising § 558.3 for increased clarity.

Elsewhere in this issue of the **Federal Register**, FDA is reproposing to remove the remaining portions of § 558.20 pertaining to arsanilic acid and arsanilate sodium.

DATES: *Effective* May 28, 1991. After the effective date, any Type A medicated article that contains phenothiazine, piperazine, or neomycin as the sole drug ingredient and that is intended for use in food-producing animals but that is not the subject of an approved NADA will be in violation of the Federal Food, Drug, and Cosmetic Act (the act) and subject to regulatory action, unless covered by a statutorily provided exception to the requirement of an approved NADA. In order to allow for an orderly phase-out, manufacture and distribution of such Type A medicated articles shall cease by August 26, 1991; the manufacture of medicated feeds (both Types B and C) from such Type A medicated articles and the distribution of such feeds shall cease by September 23, 1991; and the use of medicated feeds (both Types B and C) containing such Type A medicated articles shall cease by November 22, 1991.

FOR FURTHER INFORMATION CONTACT: William D. Price, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-4438.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 18, 1986 (51 FR 45346), FDA proposed to remove § 558.20 *Drugs used in medicated feeds in use before January 1, 1958, which are not otherwise listed;* interim listing (21 CFR 558.20) because the section did not provide an appropriate basis upon which to approve medicated feed applications and because several of the drugs listed were not the subject of approved NADA's.

FDA promulgated § 558.20 as part of a final rule (51 FR 7382; March 3, 1986) revising the procedures and requirements concerning conditions of approval for the manufacture of animal feeds containing new animal drugs. Section 558.20 was intended to list, on an interim basis, new animal drugs that had been in use in animal feeds prior to 1958 but that had not been codified in regulations published under section 512(i) of the act (21 U.S.C. 360b(i)) (46 FR 2456 at 2465, January 9, 1981; 48 FR 34574 at 34580, July 29, 1983; 51 FR 7382 at 7384, March 3, 1986). The drugs listed in § 558.20 are arsanilate sodium, arsanilic acid, butynorate (dibutyltin dilaurate), neomycin, nitarsone, phenothiazine, and piperazine.

Sections 512(a) (1) and (2), 501(a) (5) and (6), 402(a)(2)(D), and 301 of the act (21 U.S.C. 360b(a) (1) and (2), 351(a) (5) and (6), 342(a)(2)(D), and 331) forbid the use of a new animal drug in the manufacture of animal feed, and the marketing of an animal feed bearing or containing a new animal drug, unless FDA has approved: (1) An NADA for the drug for use in the feed, and; (2) a medicated feed application (MFA or FDA Form 1900) for the manufacture of the feed bearing or containing the drug, and the feed, its labeling, and its use conform to the conditions and indications of use of the NADA and the MFA.

An MFA must contain, among other things, a reference to the "regulation" that is published under section 512(i) of the act and that reflects agency approval of the NADA covering the new animal drug with which the sponsor of the MFA wishes to manufacture the medicated feed. Section 512(i) was enacted in 1968 and provides that, when it approves an NADA, FDA must publish in the **Federal Register** a "regulation" codifying the approved conditions and indications of use of the new animal drug covered by the application. The rationale for publishing approved NADA's in the form of "regulations" was simply to compile in one place a master list of all approved animal drugs, and their conditions of use, for the convenience of medicated feed manufacturers who used such information to ascertain what premixes were approved for use in their animal feeds. Animal Drug Amendments of 1967: Hearing on H.R. 3639 Before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 90th Cong., 1st sess. 43 (1967); see also statement by Rep. Nelsen, 109 Cong. Rec. 11498, 11500 (1963). Currently, there are no regulations published under