restrictions on the interstate movement of cattle from Mississippi.

Comments were solicited for 60 days after publication of the amendent. No comments were received. The factual situation which was set forth in the document of November 4, 1985, still provides a basis for the amendment.

Executive Order and Regulatory Flexibility Act

This rule is issued in conformance with Executive Order 12291 and has been determined to be not a major rule. Based on information compiled by the Department, it has been determined that this rule will not have a significant effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not have any significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the status of the State of Mississippi reduces certain testing and other requirements on the interstate movement of these cattle. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feed lots are not affected by the change in status. Also, cattle from Certified Brucellosis-Free Herds moving interstate are not affected by the change in status. It has been determined that the change in brucellosis status made by this rule will not affect marketing patterns and will not have a significant economic impact on those persons affected by this document.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V).

List of Subjects in 9 CFR Part 78

Animal diseases, Brucellosis, Cattle, Hogs, Quarantine, Transportation.

PART 78—BRUCELLOSIS

Accordingly, the interim rule amending 9 CFR Part 78 which was published at 50 FR 45808–45809 on November 4, 1985, is adopted as a final rule without change.

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done at Washington, DC, this 31st day of January 1986.

J.K. Atwell,

Deputy Administrator, Veterinary Services.

[FR Doc. 86–2535 Filed 2–4–86; 8:45 am]

BILLING CODE 3410-34-M

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9 CFR Part 92

[Docket No. 85–135]

Limited Ports; Atlanta, GA

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: This document amends the regulations in 9 CFR Part 92 by adding Atlanta, Georgia, to the list of limited ports of entry for animals and animal products (such as animal semen, animal test specimens, hatching eggs, and day old chicks) which do not appear to require restraint and holding inspection facilities. It is necessary to add Atlanta, Georgia, to this list to reflect the availability of the Veterinary Services inspection facilities and personnel so that importers can make arrangements for the importation of such animals and animal products.

DATES: Effective date of this interim rule is February 5, 1986. Written comments must be received on or before April 7, 1986.

ADDRESSES: Written comments should be submitted to Thomas O. Gessel, Director, Regulatory Coordination Staff, APHIS, USDA, Room 728, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Comments should state that they are in response to Docket Number 85–135. Written comments may be inspected at Room 728 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. S.S. Richeson, Import-Export Animals and Products Staff, VS, APHIS, USDA, Room 843, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8172.

SUPPLEMENTARY INFORMATION:

Background

The regulations in § 92.3 of 9 CFR Part 92 list a large number of ports with inspection stations or quarantine stations maintained by Veterinary Services for the importation of animals and animal products. In addition to air and ocean ports and several other types of ports, § 92.3 lists certain limited ports for the importation of animals and animal products (such as animal semen, animal test specimens, hatching eggs, and day old chicks) which do not appear to require restraint and holding inspection facilities. It has been determined that Atlanta, Georgia, has Veterinary Services inspection facilities and available inspection personnel for a limited port.

Therefore, it is necessary to amend § 92.3(e) of the regulations to add Atlanta, Georgia, as a limited port, so that importers can make arrangements for the entry of such animals and animal products.

Executive Order 12291 and Regulatory Flexibility Act

This action has been reviewed in accordance with Executive Order 12291 and has been classified as not a major rule. The Department has determined that this action will not have a significant effect on the economy; will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this rulemaking action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

It is anticipated that the addition of Atlanta, Georgia, to the list of limited ports for the importation of animals and animal products which do not appear to require restraint and holding inspection facilities would not cause a substantial change in the number of such animals and animal products entering the United States or in the number of persons importing such animals and animal products.

Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V).

Effective Date

Pursuant to the administrative procedure provisions in 5 U.S.C. 533, it is found upon good cause that prior notice and other public procedure are unnecessary and contrary to the public interest with respect to the addition of Atlanta, Georgia, to the list of limited ports in § 92.3(e), and that good cause is found for making this action effective upon publication in the **Federal Register.** Comments concerning the addition of Atlanta are being solicited for 60 days after publication of the document.

It is necessary to make this rule effective as soon as possible in order to relieve unnecessary restrictions and to reflect the existence of the Veterinary Services facility at Atlanta, so that importers of certain animals and animal products can make arrangements to utilize the facility.

List of Subjects in 9 CFR Part 92

Animal diseases, Canada, Imports, Livestock and livestock products, Mexico, Poultry and poultry products, Quarantine, Transportation, Wildlife.

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

Accordingly, Part 92, Title 9, Code of Federal Regulations, is amended as follows:

1. The authority citation for Part 92 continues to read as set forth below:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 134a, 134b, 134c, 134d, 134f, and 135; 7 CFR 2.17, 2.51, and 371.2(d).

2. Paragraph (e) of § 92.3 is revised to read:

§ 92.3 Ports designated for the importation of animals and birds.

* * * * *

(e) *Limited ports.* The following ports are designated as having inspection facilities for the entry of animals and animal products such as animal semen, animal test specimens, or hatching eggs and day old chicks which do not appear to require restraint and holding inspection facilities: Anchorage, Alaska; San Diego, California; Denver, Colorado; Jacksonville, St. Petersburg-Clearwater, and Tampa, Florida; Atlanta, Georgia; Chicago, Illinois; New Orleans, Louisiana; Portland, Maine; Baltimore, Maryland; Boston, Massachusetts; Minneapolis, Minnesota; Great Falls, Montana; Portland, Oregon; San Juan, Puerto Rico; Galveston and Houston, Texas; and Seattle, Spokane, and Tacoma, Washington.

* * * * *

Done at Washington, D.C., this 31st day of January 1986.

J. K. Atwell,

Deputy Administrator, Veterinary Services.

[FR Doc. 86–2537 Filed 2–4–86; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

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

AGENCY: Social Security Administration, HHS.

ACTION: Final rules, with request for comments on a specific rule.

SUMMARY: In these final regulations, we explain the increased widow(er)'s benefits because of the special indexing of the deceased worker's earnings when he or she died before attaining age 62. We also explain that in many cases, a widow(er) or surviving divorced spouse who remarries can nevertheless be entitled to monthly benefits after 1983 on the earnings record of a deceased insured worker. Finally, we explain that a widow(er) under age 65 may choose to have survivor's benefits begin with the month of the worker's death if the widow(er) filed in the month after death; this is an exception to the usual rule on retroactivity.

These final rules are based on sections 131, 133, and 334 of Pub. L. 98–21 (the Social Security Amendments of 1983).

DATES: These rules are effective upon publication in the **Federal Register.** Because we have revised the rule on remarriage (§ 404.336) since the Notice of Proposed Rulemaking was published, comments on this final rule may be submitted within 60 days after publication.

ADDRESSES: Comments on the remarriage rule should be submitted in writing to the Acting Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, Maryland 21203, or delivered to the Office of Regulations, Social Security Administration, 3–A–3 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235 between 8:00 a.m. and 4:30 p.m. on regular business days. Comments received may be inspected during these same hours by making arrangments with the contact person shown below. If appropriate, we will respond in a future publication to any comments we receive on the revised remarriage rule.

FOR FURTHER INFORMATION CONTACT: Jack Schanberger, Room 3–B–4 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235, (301) 594–6785.

SUPPLEMENTARY INFORMATION:

Remarriage of Widow(er)

Before the Social Security Amendments of 1983, a person could not be entitled to benefits as a widow or a widower if he or she had remarried before age 60 and was still married. Also, the deceased worker's surviving divorced spouse who had remarried at any age and was still married could not be entitled to widow(er)'s benefits. Furthermore, if a surviving spouse under age 60 or a surviving divorced spouse of any age remarried after becoming entitled to widow's or widower's benefits, entitlement ended unless the remarriage was to a person entitled to certain kinds of Social Security benefits (see 20 CFR 404.337). Under the provisions of the 1983 Amendments, remarriage after attaining age 60 does not affect a widow(er)'s or surviving divorced spouse's continuing entitlement to benefits. Remarriage at age 50–59 prevents entitlement of a person in that age bracket if he or she remarries before meeting the disability requirement (§§ 404.335(c) and 404.336(c)) for entitlement before age 60. Remarriage at age 50–59 prevents entitlement of a person after attaining age 60 if the person remarried before he or she was entitled to benefits as a disabled widow(er) and recovered from the disabling condition prior to attaining age 60. This provision removes the distinction between surviving spouses and surviving divorced spouses who remarry after attaining age 60. It also removes the requirement that a disabled surviving spouse under age 60 and a surviving divorced spouse age 50 or older who remarries cannot continue to

receive benefits unless the marriage is to a certain category of Social Security beneficiary.

The 1983 Amendments also amended the section of the Act (section 202(f)) on widower's benefits by providing for the entitlement of a surviving divorced husband. This makes section 202(f) consistent with the existing provisions of the Act on benefits for surviving divorced wives and reflects the decision of the District Court for the District of Oregon in *Ambrose* v. *Califano* (July 17, 1980). Our regulations have included this provision in 20 CFR 404.336 since March 22, 1982 (47 FR 12162).

The 1983 Amendments further amended the section of the Act on widower's benefits by changing the entitlement requirement "has not married" to "is not married." This too is consistent with the provisions on benefits for widows and follows the decision of the District Court for the Southern District of Texas in *Mertz* v. *Harris* (September 10, 1980). Our regulations have included this provision in 20 CFR 404.335 and 404.336 since March 22, 1982 (47 FR 12162).

In these final regulations, we are revising the rule on remarriage as it was published in the Notice of Proposed Rulemaking. We specify that the surviving divorced spouse's remarriage must have occurred after the insured individual died. This rule will not be consistent with the rule for a divorced spouse of a living insured individual (see §§ 404.331 and 404.332), which requires that the spouse not have married in or before the first month for which he or she could be entitled. More important, it will reflect the intent of Congress as expressed in the language of section 131 of the 1983 Amendments and in legislative history (Senate Rep. No. 98–23, 98th Cong., 1st Sess. (1983) at page 6). We are further revising the rule on remarriage of a surviving divorced spouse by providing that such a spouse may be entitled only for months after 1983 if he or she remarried after reaching age 60 and does not meet a disability requirement. (In the Notice of Proposed Rulemaking, we did not limit such a spouse's entitlement to months after 1983.)

Indexing Deceased Worker's Earnings

Under the Act in effect before the 1983 Amendments, benefit amounts for a widow(er) of an insured worker who would have reached age 62 after 1978 and who died before age 62 are usually based on the worker's earnings from 1951 through the year of death. Further, earnings from 1951 through the second year before death are indexed (i.e, updated) to reflect the level of the average wages of all workers for the second year before the worker's death. If the surviving spouse does not become entitled until some year after the worker's death, the spouse is disadvantaged because his or her benefits do not reflect the economy-wide wage increases that would have increased the worker's indexed earnings had he or she lived longer. The 1983 Amendments remedy this disadvantage by providing that where the worker dies before age 62, the indexing will be based on the average wage level of all workers near the time the widow(er) becomes eligible for survivor's benefits. We will only pay the benefit computed under this provision if the amount is greater than that computed under the pre-amendment provisions.

We are modifying 20 CFR 404.212(b)(1) as stated in the Notice of Proposed Rulemaking by providing that we will compute the primary insurance amount as if the deceased worker had not died but reached age 62 in the second year after the appropriate indexing year. This is a clarification of the former language where we said that we will compute as if the deceased worker had died in the second year after the indexing year.

Retroactivity of Widow(er)'s Benefits

Before the 1983 Amendments, the Act provided that a person could not be entitled to benefits for any month before the month in which an application is filed if the benefit amount beginning in a prior month would be reduced or further reduced because the person was under age 65. The 1983 Amendments provide an exception for a widow(er) who files in the month after the worker died. Such a widow(er) may be entitled beginning with the month of the worker's death, even if his or her benefit amount will be less because of the earlier entitlement. This provision offers protection if the worker dies late in a month and the widow(er) under age 65 does not file until the next month.

Effective Dates

The legislative provision on remarriage is effective for benefits for months after December 1983; a person who is not entitled for December 1983 must file an application. The legislative provision on indexing is effective for benefits for months after December 1984 for widows and widowers who are first eligible after December 1984. The legislative provision on retroactivity is effective for applications filed on or after July 1, 1983.

Comments

These rules were published as a Notice of Proposed Rulemaking at 49 FR 22340 on May 29, 1984. We received no comments. We are, therefore, adopting these rules as proposed, except as otherwise stated.

Regulatory Procedures

Executive Order 12291—These final regulations have been reviewed under E.O. 12291 for their estimated program costs or savings for FY 1984–88. The provisions on indexing are expected to increase program costs by $4 million, the remarriage provisions by $109 million, and the retroactivity of benefits provisions by a negligible amount. However, these provisions are required by Pub. L. 98–21 and we have no discretion in implementing them. Therefore, OMB has waived the requirement that a regulatory impact analysis be prepared.

Paperwork Reduction Act—The final regulations impose no reporting/recordkeeping requirements requiring OMB 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 benefit amounts payable to individuals. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Programs No. 13.805 Social Security—Survivors Insurance)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-age, survivors, and disability insurance, Social Security.

Dated: September 16, 1985.

Martha A. McSteen,

Acting Commissioner of Social Security.

Approved: November 25, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

Subparts C, D, and G of Part 404 of Chapter III of Title 20 of the Code of Federal Regulations are amended as follows:

PART 404—[AMENDED]

1. The authority citation for Subpart C is revised to read as follows:

Authority: Secs. 202, 205, 215, and 1102, Social Security Act, 49 Stat. 623, as amended; 53 Stat. 1368, as amended; 64 Stat. 506, as amended, 49 Stat. 647, as amended, 42 U.S.C. 402, 405, 415, and 1302.

2. Section 404.211 is amended by revising paragraph (d)(1) and by adding a new paragraph (d)(4) to read as follows:

§ 404.211 Computing your average indexed monthly earnings.

* * * * *

(d) *Indexing your earnings.* (1) The first step in indexing your social security earnings is to find the relationship (under paragraph (d)(2)) between—

(i) The average wage of all workers in your computation base years; and

(ii) The average wage of all workers in your "indexing-year." As a general rule, your indexing year is the second year before the earliest of the year you reach age 62, or become disabled or die before age 62. However, your indexing year is determined under paragraph (d)(4) of this section if you die before age 62, your surviving spouse or surviving divorced spouse is first eligible for benefits after 1984, and the indexing year explained in paragraph (d)(4) results in a higher widow(er)'s benefit than results from determining the indexing year under the general rule.

* * * * *

(4) We calculate your indexing year under this paragraph if you, the insured worker, die before reaching age 62, your surviving spouse or surviving divorced spouse is first eligible after 1984, and the indexing year calculated under this paragraph results in a higher widow(er)'s benefit than results from the indexing year calculated under the general rule explained in paragraph (d)(1)(ii). For purposes of this paragraph, the indexing year is never earlier than the second year before the year of your death. Except for this limitation, the indexing year is the earlier of—

(i) The year in which you, the insured worker, attained age 60, or would have attained age 60 if you had lived, and

(ii) The second year before the year in which the surviving spouse or the surviving divorced spouse becomes eligible for widow(er)'s benefits, i.e. has attained age 60, or is age 50–59 and disabled.

* * * * *

3. Section 404.212 is amended in paragraph (b)(1) by adding the following 3 sentences to the end thereof, and by removing the authority citation at the end of the section, to read as follows:

§ 404.212 Computing your primary insurance amount from your average indexed monthly earnings.

* * * * *

(b) *Benefit formula.* (1) * * * If you die before age 62, and your surviving spouse or surviving divorced spouse is first eligible after 1984, we may compute the primary insurance amount, for the purpose of paying benefits to your widow(er), as if you had not died but reached age 62 in the second year after the indexing year that we computed under the provisions of § 404.211(d)(4). We will not use this primary insurance amount for computing benefit amounts for your other survivors or for computing the maximum family benefits payable on your earnings record. Further, we will only use this primary insurance amount if it results in a higher widow(er)'s benefit than would result if we did not use this special computation.

* * * * *

4. The authority citation for Subpart D is revised to read as follows:

Authority: Secs. 202, 205, 216, 223, 228, 1102 of the Social Security Act, 49 Stat. 623, 53 Stat. 1368, 64 Stat. 492, 64 Stat. 510 as amended, 70 Stat. 815, 80 Stat. 67, 49 Stat. 647; Sec. 5, Reorganization Plan No. 1 of 1953, 67 Stat. 631; 42 U.S.C. 402, 405, 416, 423, 428, and 1302; and 5 U.S.C. Appendix.

5. Section 404.335 is amended by revising paragraph (e) and by deleting the authority citation at the end of the section, to read as follows:

§ 404.335 Who is entitled to widow's or widower's benefits.

* * * * *

(e) You are unmarried, unless—

(1) You remarried after you became 60 years old; or

(2) For benefits for months after 1983—

(i) You are now age 60 or older;

(ii) You remarried after attaining age 50 but before attaining age 60; and

(iii) At the time of the remarriage, you were entitled to widow(er)'s benefits as a disabled widow(er); or

(3) For benefits for months after 1983—

(i) You are now at least age 50 but not yet age 60;

(ii) You remarried after attaining age 50; and

(iii) You met the disability requirements in paragraph (c) of this section at the time of your remarriage (i.e., your disability began within the specified time and before your remarriage).

6. Section 404.336 is amended by revising paragraph (e) and by deleting the authority citation at the end of the section, to read as follows:

§ 404.336 Who is entitled to widow's or widower's benefits as a surviving divorced spouse.

* * * * *

(e) You are unmarried, unless for benefits for months after 1983—

(1) You remarried after you became 60 years old; or

(2)(i) You are now age 60 or older;

(ii) You remarried after attaining age 50 but before attaining age 60; and

(iii) At the time of the remarriage, you were entitled to widow(er)'s benefits as a disabled widow(er); or

(3)(i) You are now at least age 50 but not yet age 60;

(ii) You remarried after attaining age 50; and

(iii) You met the disability requirements in paragraph (c) of this section at the time of your remarriage (i.e., your disability began within the specified time and before your remarriage).

(4) In addition to meeting the requirements of paragraph (e)(1), (e)(2), or (e)(3) of this section, you remarried after the insured person died.

§404.337 [Amended]

7. Section 404.337 is amended by removing paragraph (b)(1) and by redesignating paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) as (b)(1), (b)(2), (b)(3), and (b)(4) respectively.

§404.338 [Amended]

8. Section 404.338 is amended by adding new material between the first and second sentences to read as follows:

* * * If the insured person died before reaching age 62 and you are first eligible after 1984, we may compute a special primary insurance amount for the purpose of determining the amount of your monthly benefit (see § 404.212(b)). We may increase your monthly benefit amount if the insured person earned delayed retirement credit after age 65 by working or by delaying filing for benefits (see § 404.313). * * *

9. The authority citation for Subpart G is revised to read as follows:

Authority: Secs. 202(j)(1), 205 and 1102 of the Social Security Act, 53 Stat. 1368, and 49 Stat. 623, 624, and 647; sec. 5, Reorganization Plan No. 1 of 1953, 67 Stat. 631, 94 Stat. 2655; 42 U.S.C. 402(j)(1), 405 and 1302 and 5 U.S.C. appendix.

10. Section 404.621 is amended by revising the first sentence of paragraph (a)(2)(iii), by adding a new paragraph (a)(2)(iv) and by removing the authority citation at the end of the section, to read as follows:

§ 404.621 Filing after the first month you meet the requirements for benefits.

(a) * * *

(2) * * *

(iii) You are a widow, widower, surviving divorced wife, or surviving divorced husband who is disabled and

could be entitled to retroactive benefits for any month before age 60.

* * * * *

(iv) You are a widow, widower, or surviving divorced spouse of the insured person who died in the month before you applied and you were at least age 60 in the month of death of the insured person on whose earnings record you are claiming benefits. In this case, you can be entitled beginning with the month the insured person died if you choose and if you file your application on or after July 1, 1983.

[FR Doc. 86-2364 Filed 2-4-86; 8:45 am]

BILLING CODE 4190-11-M

Food and Drug Administration

21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Amoxicillin Trihydrate and Clavulanate Potassium for Oral Suspension

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 by Beecham Laboratories, providing for use of amoxicillin trihydrate and clavulanate potassium for oral suspension in dogs for the treatment of certain skin and soft tissue infections such as wounds, abscesses, cellulitis, and superficial/juvenile and deep pyoderma.

EFFECTIVE DATE: February 5, 1986.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham Inc., Bristol, TN 37620, filed NADA 55-101 for Clavomox ® (amoxicillin trihydrate and clavulanate potassium) Oral Suspension (Drops) for use in dogs. The drug is a dry powder which is reconstituted for the treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, and superficial/juvenile and deep pyoderma due to beta-lactamase (penicillinase) producing *Staphylococcus aureus*, non-beta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp. *Streptococcus* spp. and *E. coli*. The application is approved and the regulations are amended accordingly. 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, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(4).

List of Subjects in 21 CFR Part 540

Aninal 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, Part 540 is amended as follows:

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

1. The authority citation for 21 CFR Part 540 continues to read as follows:

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

2. By adding new § 540.103h to read as follows:

§ 540.103h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate and clavulanate potassium for oral suspension is a dry mixture of amoxicillin trihydrate and clavulanate potassium with one of more suitable and harmless flavorings, sweetening ingredients, stabilizers, and suspending agents. When reconstituted as directed in the labeling, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid. Its amoxicillin trihydrate content is satisfactory if it is not less that 90 percent and not more than 120 percent of the number of milligrams of amoxicillin that it is represented to contain. Its clavulanate is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of clavulanic acid that it is represented to contain. The moisture content of the dry powder is not more than 8.5 percent. When reconstituted as directed in the labeling, its pH is not less than 4.8 and not more than 6.6. The amoxicillin trihydrate conforms to the standards prescribed by § 440.3(a)(1) of this chapter. The calvulanate potassium conforms to the standards prescribed by § 455.15(a)(1) of this chapter.

(2) *Labeling.* The drug shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter; in addition, it shall be labeled "amoxicillin and clavulanate potassium for oral suspension, veterinary".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The amoxicillin trihydrate used in making the batch for potency, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(*b*) The clavulanate potassium used in making the batch for clavulanic acid content, moisture, pH, identity, and clavam-2-carboxylate content.

(*c*) The batch for amoxicillin content, clavulanic acid content, moisture, and pH.

(ii) Samples required:

(*a*) The amoxicillin trihydrate used in making the batch: 12 packages, each containing approximately 300 milligrams.

(*b*) The clavulanate potassium used in making the batch: 12 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Amoxicillin and clavulanic acid contents.* Proceed as in § 440.103e(b) of this chapter.

(2) *Moisture.* Proceed as in § 436.201 of this chapter.

(3) *pH.* Proceed as in § 436.202 of this chapter, using the suspension reconstituted as directed in the labeling.

(c) *Conditions of marketing*—(1) *Specifications.* The drug conforms to the requirements of paragraph (a) of this section.