areas south of the United States must land for CBP processing.

Authority

This change is made under the authority of 5 U.S.C. 301, 19 U.S.C. 1433, 1644a, 1624, and 6 U.S.C. 203.

The Regulatory Flexibility Act and Executive Order 12866

This amendment expands the list of designated airports at which certain aircraft may land for customs processing. As described in this document, certain international flights have been arriving at SAT, pursuant to statute, from November 2000, through November 9, 2006. The expansion of the list of designated airports to include SAT will not result in any new impact on affected parties but will result in a continuation of the previous situation. Therefore, CBP certifies that this rule will not have significant economic impact on a substantial number of small entities. Accordingly, the document is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Office of Management and Budget has determined that this rule is not a significant regulatory action as defined under Executive Order 12866.

Signing Authority

This amendment to the regulations is being issued in accordance with 19 CFR 0.2(a) pertaining to the authority of the Secretary of Homeland Security (or his or her delegate) to prescribe regulations not related to customs revenue functions.

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendments to Regulations

■ Part 122, Code of Federal Regulations (19 CFR part 122) is amended as set forth below:

PART 122—AIR COMMERCE REGULATIONS

■ 1. The authority citation for part 122, 19 CFR, continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

* * * * *

§ 122.24 [Amended]

■ 2. In § 122.24(b) the chart is amended by adding to the list of airports, in alphabetical order in the ''Location'' column, ''San Antonio Tex'' and on the same line, in the ''Name'' column, ''San Antonio International Airport.''

Dated: March 3, 2008.

Michael Chertoff,

Secretary.

[FR Doc. E8–4578 Filed 3–6–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Forms; Cephapirin Benzathine

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 new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for a revision to the labeling of cephapirin benzathine intramammary infusion administered to dairy cows entering their dry period for the treatment of mastitis.

DATES: This rule is effective March 7, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 108–114 that revises labeling of CEFA-DRI (cephapirin benzathine) Intramammary Infusion administered to dairy cows entering their dry period for the treatment of mastitis. The application is approved as of February 7, 2008, and the regulations are amended in 21 CFR 526.363 to reflect the approval, an editorial change, and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 526

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 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 1. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.363 [Amended]

■ 2. In § 526.363, at the end of paragraph (d)(2), add '', including penicillin-resistant strains''; and in the second sentence of paragraph (d)(3), remove ''use'' and add in its place ''used''.

Dated: February 27, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–4473 Filed 3–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA–2008–N–0135] (formerly Docket No. 2007N–0284]

Revision of the Requirements for Live Vaccine Processing; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of March 18, 2008, for the direct final rule that appeared in the **Federal Register** of October 18, 2007 (72 FR 59000). The direct final rule amends the biologics regulations by providing options to the existing requirements for the processing of live vaccines. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: March 18, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2007 (72 FR 59000), FDA solicited comments concerning the direct final rule for a 75-day period ending January 2, 2008. FDA stated that the effective date of the direct final rule would be on March 18, 2008, 75 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA received two letters of comment on the direct final rule. However, neither of these constitutes significant adverse comment. Therefore, FDA is confirming the effective date of the direct final rule. The two comments received were from private industry and an individual. The comments received and FDA's responses to the comments are discussed as follows:

Both comments requested clarification of the change under the new 21 CFR 600.11(e)(4)(i)(B), the language for which was taken directly from the existing 21 CFR 600.11(e)(4). One comment asked whether the requirements under this section are intended to cover research and development. The comment also asked for the definition of ''microorganism'' and whether ''test'' refers to viral inactivation.

The new provision mirrors the last sentence in the existing provision. The requirements under 21 CFR 600.11(e)(4)(i)(B) apply to buildings and equipment used for the manufacture of biological products regulated by FDA, not for research and development. We do not believe it is necessary to define the term ''microorganism,'' as this is a generally understood term, and is used throughout 21 CFR part 600. The terms ''test'' and ''test procedures'' do not refer to manufacturing steps such as viral inactivation.

Another comment asked whether the industry practice of using biological indicators for equipment or materials sterilization qualification is consistent with the requirements in new 21 CFR 600.11(e)(4)(i)(B).

This direct final rule does not apply to microorganisms used as biological indicators for validation, qualification or monitoring of sterilization cycles. The rule does not change the requirements for those products set forth in 21 CFR 600.11(e)(2).

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby become effective on March 18, 2008.

Dated: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4471 Filed 3–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9385]

RIN 1545–BG65

Diversification Requirements for Variable Annuity, Endowment, and Life Insurance Contracts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning the diversification requirements of section 817(h) of the Internal Revenue Code (Code). The regulations expand the list of holders whose beneficial interests in an investment company, partnership, or trust do not prevent a segregated asset account from looking through to the assets of the investment company, partnership, or trust, to satisfy the requirements of section 817(h). The regulations also remove the sentence in § 1.817–5(a)(2) that provides that the payment required to remedy an inadvertent diversification failure must be based on the tax that would have been owed by the policyholders if they were treated as receiving the income on the contract. The regulations affect insurance companies that issue variable contracts and affect policyholders who purchase such contracts.

DATES: *Effective/applicability date:* These regulations are effective as of *March 7, 2008.*

FOR FURTHER INFORMATION CONTACT: James Polfer, (202) 622–3970 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 817(d) defines a variable contract for purposes of part I of subchapter L of the Code (sections 801–818). For a contract to be a variable contract, it must provide for the allocation of all or a part of the amounts received under the contract to an account that, pursuant to state law or regulation, is segregated from the general asset accounts of the issuing insurance company. In addition, for a life insurance contract to be a variable contract, it must qualify as a life insurance contract for Federal income tax purposes, and the amount of the death benefits (or the period of coverage) must be adjusted on the basis of the investment return and the market value of the segregated asset account; for an annuity contract to be a variable contract, it must provide for the payment of annuities, and the amounts paid in, or the amount paid out, must reflect the investment return and the market value of the segregated asset account; for a contract that provides funding of insurance on retired lives to be a variable contract, the amounts paid in, or the amounts paid out, must reflect the investment return and the market value of the segregated asset account.

Section 817(h)(1) provides that a variable contract that is based on a segregated asset account is not treated as an annuity, endowment, or life insurance contract unless the segregated asset account is adequately diversified in accordance with regulations prescribed by the Secretary. If a segregated asset account is not adequately diversified for a calendar quarter, then the contracts supported by that segregated asset account are not treated as annuity, endowment, or life insurance contracts for that period and subsequent periods, even if the segregated asset account is adequately diversified in those subsequent periods. Under § 1.817–5(a), if a segregated asset account is not adequately diversified, income earned by that segregated asset account is treated as ordinary income received or accrued by the policyholders. Section 1.817–5(a)(2) provides conditions an issuer of a variable contract must satisfy in order to correct an inadvertent failure to diversify. Rev. Proc. 92–25, 1992–1 CB 741, see § 601.601(d)(2) of this chapter, sets forth in more detail the procedure by which an issuer may request the relief described in § 1.817–5(a)(2).

Congress enacted the diversification requirements of section 817(h) to ''discourage the use of tax-preferred variable annuity and variable life insurance primarily as investment vehicles.'' H.R. Conf. Rep. No. 98–861, at 1055 (1984). In section 817(h)(1), Congress granted the Secretary broad regulatory authority to develop rules to carry out this intent. Congress directed that these standards be imposed because ''by limiting a customer's ability to