

Supplemental NADA is approved as of May 29, 2001, and the regulations are amended in 21 CFR 522.313 to reflect the approval. The basis of 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 supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning May 29, 2001, because the supplement application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental application and conducted or sponsored by the applicant.

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.

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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.313 [Amended]

2. Section 522.313 *Ceftiofur sodium powder for injection* is amended in

paragraph (d)(1)(i) by adding after "intramuscularly" the phrase "or subcutaneously".

Dated: June 7, 2001.

Claire M. Lathers,

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

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 3697]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended: Aliens Ineligible To Transit Without Visas (TWOV)—Russia

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Interim rule with request for comments.

SUMMARY: Section 212(d)(4)(A) of the Immigration and Nationality Act (INA) permits the Secretary of State, acting jointly with the Attorney General, to waive the visa and passport requirement of INA 212(a)(7)(B) for certain aliens in direct transit through the United States. This waiver allows an alien to transit the United States without a passport and visa provided the alien is traveling on a carrier signatory to an agreement with the Immigration and Naturalization Service (INS) in accordance with INA 233(c) and bears documentation establishing identity and nationality which permits the alien's entry into another country. This rule removes Russia from the list of countries that are ineligible to transit without visa (TWOV) that was published on January 5, 2001 at 66 FR 1033.

DATES: *Effective Date:* This interim rule is effective June 15, 2001.

Comment Date: Written comments may be submitted sixty days from August 14, 2001.

ADDRESSES: Submit comments, in duplicate, to the H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20522-0106; or e-mail: odomhe@state.gov.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Room L603-C, SA-1, Department of State, Washington, DC 20520-0106, or phone (202) 663-1204; or e-mail: odomhe@state.gov.

SUPPLEMENTARY INFORMATION:

What Is the Authority for Allowing or Prohibiting Transit Without Visa?

Section 212(d)(4)(C) of the Immigration and Nationality Act (INA) provides the authority for the Secretary of State, acting jointly with the Attorney General, to waive the passport and/or visa requirement for a nonimmigrant who is in immediate and continuous transit through the United States and is using a carrier that has entered into a Transit Without Visa (TWOV) Agreement as provided in INA 233(c).

Who Determines Which Countries Can Transit Without a Visa?

Since TWOV does not involve the issuance of a visa, the Department's role in the day-to-day administration of the TWOV program is minimal. Therefore, the Department's regulation at 22 CFR 41.2(i), for the most part, is merely a restatement of the INS regulation on the same subject. The Department does become involved, however, in the designation of those countries whose citizens are ineligible to utilize the TWOV. The current regulation provides a list of ineligible countries.

Which Countries Are Removed From the List of Countries Whose Citizens Cannot TWOV?

This rule removes Russia from the list of countries whose citizens cannot TWOV.

Why Is Russia Being Removed From the List of Countries Whose Citizens Cannot TWOV?

The Department and the INS have reviewed again the current list of ineligible countries and have determined that Russia can be removed from the list. In making the decision to remove Russia from the list the agencies took into consideration, in addition to the criteria specified in the regulation, comments received which expressed concern about the commercial impact caused by placing Russia on the list. Specifically, the withdrawal of TWOV privileges for Russia would discourage travel by Russian nationals and thus would have a serious negative impact on airline and port-of-entry revenues.

What Other Amendments Are Being Made?

In the interim regulation the entry for "Serbia" is amended to read "Federal Republic of Yugoslavia". On November 17, 2000, the United States recognized the Federal Republic of Yugoslavia as an independent state. Therefore, the former reference to Serbia and Montenegro is now listed as the Federal Republic of Yugoslavia.

Interim Rule*How Will the Department of State Amend Its Regulations?*

This rule and the INS rule published elsewhere in this issue amend the list of countries found at 22 CFR 41.2(i) whose citizens the Department and the INS have determined are not eligible for the transit without visa (TWOV) program.

Administrative Procedure Act

The Department is implementing this rule as an interim rule, with a 60-day provision for post-promulgation public comments, based on the "good cause" exceptions found at 5 U.S.C. 553(b)(B) and 553(d)(3). Since this rule bestows a benefit for Russian nationals traveling to the U.S., the Department is implementing this rule immediately.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

Although this rule is promulgated in conjunction with the Immigration and Naturalization Service, a domestic agency, the Department of State does not consider this rule to be a "significant regulatory action" under Executive Order 12866, section 3(f) Regulatory Planning and Review.

Therefore, in accordance with the letter to the Department of State of February 4, 1994 from the Director of Management and Budget, it does not require review by the Office of Management and Budget.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements. The information collection requirement (Form OF-156) contained by reference in this rule was previously approved for use by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

List of Subjects in 22 CFR Part 41

Aliens, Foreign officials, Passports and visas.

In view of the foregoing, the Department amends 22 CFR as follows:

PART 41—[AMENDED]

1. The authority citation for 22 CFR part 41 continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105-277, 112 Stat. 2681 et. seq.

2. Amend § 41.2 by revising paragraph (i)(2) to read as follows:

§ 41.2 Waiver by Secretary of State and Attorney General of passport and/or visa requirements for certain categories of nonimmigrants.

* * * * *

(i) * * *

(2) Notwithstanding the provisions of paragraph (i)(1) of this section, this waiver is not available to an alien who is a citizen of: Afghanistan, Angola, Bangladesh, Belarus, Bosnia-Herzegovina, Burma, Burundi, Central African Republic, People's Republic of China, Colombia, Congo (Brazzaville), India, Iran, Iraq, Libya, Nigeria, North Korea, Pakistan, Sierra Leone, Somalia, Sri Lanka, Sudan, or the Federal Republic of Yugoslavia.

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Dated: June 6, 2001.

Mary A. Ryan,

*Assistant Secretary for Consular Affairs,
Department of State.*

[FR Doc. 01-15051 Filed 6-14-01; 8:45 am]

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 1, 31, 301, and 602**

[TD 8947]

RIN 1545-AY79

Penalties for Underpayments of Deposits and Overstated Deposit Claims

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of final regulations.

SUMMARY: This document makes conforming amendments to certain final regulations to reflect the removal of final regulations relating to the penalty for underpayment of deposits of taxes and the penalty for overstated deposit claims. These regulations are obsolete due to amendments to section 6656 of the Internal Revenue Code. The removal of these regulations will not affect taxpayers.

DATES: The amendments and removals are effective June 15, 2001.

FOR FURTHER INFORMATION CONTACT: Robin M. Tuczak, (202) 622-4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background and Explanation of Provisions**

This document removes two sections from the Procedure and Administration Regulations (26 CFR part 301) relating to penalties for underpayment of Federal tax deposits and overstated deposit claims under section 6656 of the Internal Revenue Code. The Omnibus Budget Reconciliation Act of 1989, Public Law 101-239 (103 Stat. 2106, 1989) amended section 6656, modifying the penalty rates relating to a failure to make a Federal tax deposit and removing the penalty relating to overstatement of Federal tax deposits. These changes have rendered §§ 301.6656-1 and 301.6656-2 obsolete.

Section 301.6656-1 was revised and § 301.6656-2 was added by TD 7925, published in the **Federal Register** for December 13, 1983 (LR-311-81, 48 FR 5453). Section 301.6656-2 was added to implement changes made by the