express reference to this requirement in the instruction to Item 3.A was not intended to signal a change in policy. Finally, the amendment corrects various cross-references in Forms F–2 and F–3 under the Securities Act of 1933.

Certain Findings

Under the Administrative Procedure Act (''APA''), notice of proposed rulemaking is not required when an agency, for good cause, finds ''that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [2] The correcting amendments to Form 20–F and Forms F–2 and F–3 are technical changes that (1) clarify that there is no change in the long-standing requirement for full period, audited financial statements; (2) incorporate the long-standing practice of accepting two years income statement and cash flow information for filers presenting financial information in accordance with U.S. GAAP; (3) reconcile the instructions to Item 3.A and Item 8 of Form 20–F; and (4) correct cross-references in the forms. For these reasons, the Commission finds that there is no need to publish notice of these amendments.[3]

The APA also requires publication of a rule at least 30 days before its effective date unless the agency finds otherwise for good cause.[4] For the same reasons described with respect to opportunity for notice and comment, the Commission finds there is good cause for the amendments to take effect immediately.

List of Subjects in 17 CFR Parts 239 and 249

Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, the Commission amends Title 17, chapter II of the Code of Federal Regulations as follows:

[2] 5 U.S.C. 553(b)(3)(B).

[3] For similar reasons, the amendments do not require analysis under the Regulatory Flexibility Act or analysis of major rule status under the Small Business Regulatory Enforcement Fairness Act. *See* 5 U.S.C. 601(2) (for purposes of Regulatory Flexibility Act analyses, the term ''rule'' means any rule for which the agency publishes a general notice of proposed rulemaking); 5 U.S.C. 804(3)(C) (for purposes of congressional review of agency rulemaking, the term ''rule'' does not include any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties).

[4] *See* U.S.C. 553(d)(3).

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

1. The authority citation for part 239 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77sss, 78c, 78*l,* 78m, 78n, 78o(d), 78u–5, 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79*l,* 79m, 79n, 79q, 79t, 80a–8, 80a–24, 80a–29, 80a–30 and 80a–37, unless otherwise noted.

* * * * *

2. Amend Form F–2 (referenced in § 239.32) Item 4 by removing the words ''Item 10 (The Offer and Listing)'' and adding in their place the words ''Item 9 (Offer and Listing), Item 10 (Additional Information)''.

Note: The text of Form F–2 does not and this amendment will not appear in the Code of Federal Regulations.

3. Amend Form F–3 (referenced in § 239.33) Item 4 by removing the words ''Item 10 (The Offer and Listing)'' and adding in their place the words ''Item 9 (Offer and Listing), Item 10 (Additional Information)''.

Note: The text of Form F–3 does not and this amendment will not appear in the Code of Federal Regulations.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

4. The authority citation for part 249 continues to read, in part, as follows:

Authority: 15 U.S.C. 78a, *et seq.*, unless otherwise noted.

* * * * *

5. Amend Form 20–F (referenced in § 249.220f) by:

a. In Item 3, designate the current text of Instructions to Item 3.A as Instruction 2 and add new Instruction 1;

b. In Item 8, paragraph 1 to Instructions to Item 8.A.4, remove the last sentence; and

c. In Item 8, add Instruction 3 to Instructions to Item 8.A.2 to read as follows:

Note: The text of Form 20-F does not and this amendment will not appear in the Code of Federal Regulations.

Securities and Exchange Commission

OMB Approval
OMB Number: 3235–0288
Expires: June 20, 2002
Estimated average burden hours per response—1991.00

Form 20–F—Registration Statement Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

* * * * *

Instructions to Item 3.A

1. This item refers to the company, but note that in some cases, you may have to provide selected financial data for a predecessor. See the definition of predecessor in Exchange Act Rule 12b–2 and Securities Act Rule 405.

2. * * *

* * * * *

Instructions to Item 8.A.2

1. * * *

3. In initial registration statements, if the financial statements presented pursuant to Item 8.A.2 are prepared in accordance with U.S. generally accepted accounting principles, the earliest of the three years may be omitted if that information has not previously been included in a filing made under the Securities Act of 1933 or the Securities Exchange Act of 1934. Selected financial data presented pursuant to Item 3.A of Form 20–F for the full five fiscal years is still required.

* * * * *

June 11, 2001.
By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–15137 Filed 6–14–01; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Sterile Powder for Injection

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 Pharmacia and Upjohn Co. The supplemental NADA provides for subcutaneous injection of a solution of reconstituted ceftiofur sodium powder in cattle.

DATES: This rule is effective June 15, 2001.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 140–338 that provides for use of Naxcel® (ceftiofur sodium) sterile powder for injection by subcutaneous injection of a solution of reconstituted ceftiofur sodium powder in cattle for the treatment of several bacterial diseases.

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.

[FR Doc. 01–15083 Filed 6–14–01; 8:45 am]

BILLING CODE 4160–01–S

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.