

reference. The intended effect of this rule is to provide adequate controlled airspace for IFR operations at Chevak Airport, Chevak, Alaska.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule 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 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71— DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, *Airspace Designations and Reporting Points*, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Chevak, AK [New]

Chevak Airport, AK
(Lat. 61°31′01″ N., long. 165°35′01″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Chevak Airport excluding that

airspace within the Hooper Bay, Alaska Class E Airspace area.

* * * * *

Issued in Anchorage, AK, on October 27, 2003.

Trent S. Cummings,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 03–28820 Filed 11–18–03; 8:45 am]

BILLING CODE 4910–13–P

INTERNATIONAL TRADE COMMISSION

19 CFR Part 206

Investigations Relating to Global and Bilateral Safeguard Actions, Market Disruption, Trade Diversion, and Review of Relief Actions

AGENCY: International Trade Commission.

ACTION: Interim rules with request for comments.

SUMMARY: The United States International Trade Commission (Commission) amends its interim Rules of Practice and Procedure for investigations relating to alleged market disruption from imports from China. These amendments are necessary to respond to exigencies created by statutory time constraints and to address concerns created by the existing rules. The intended effect of the amendments is to resolve concerns created by the existing rules, codify actual Commission practice, and provide consistency in and greater transparency regarding the subject Commission investigations.

DATES: Effective Date: These amendments are effective as of November 19, 2003, but do not apply to petitions filed on or before the effective date or to investigations in progress as of the effective date.

Comment Date: The deadline for filing written comments on the amendments is 5:15 p.m. on January 20, 2004. The comments must arrive at the address listed below by that deadline in order to receive consideration by the Commission and its staff. See sections 201.3 and 201.8 of the Commission’s Rules of Practice and Procedure (19 CFR 201.3 and 201.8).

ADDRESSES: A signed original and 3 copies of each set of comments on these amendments to the Commission’s rules, along with a cover letter, should be submitted by mail or hand-delivery to Marilyn R. Abbott, Secretary, United States International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436. Comments may

be submitted electronically to the extent provided by section 201.8 of the Commission’s rules, as amended at 67 FR 68063 (Nov. 8, 2002) and 68 FR 32971 (June 4, 2003).

FOR FURTHER INFORMATION CONTACT:

William W. Gearhart, Esq., Office of the General Counsel, United States International Trade Commission, telephone 202–205–3091. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal at 202–205–1810. General information concerning the Commission also may be obtained by accessing its Internet server, <http://www.usitc.gov>.

SUPPLEMENTARY INFORMATION: The preamble below is designed to assist readers in understanding the interim amendments the Commission is making to its Rules of Practice and Procedure in part 206. The preamble begins with a discussion of the background of the rulemaking, then explains why an interim rulemaking procedure was adopted, provides a section-by-section analysis of the interim amendments, and ends with a regulatory analysis addressing government-wide statutes and issuances on rulemaking. The Commission encourages members of the public to comment—in addition to any other comments they wish to make regarding the amendments—on whether the amendments are in language that is sufficiently plain for users of the rules to understand.

Background

Section 421(b) of the Trade Act of 1974, as amended, requires the Commission to investigate, in specified circumstances, “to determine whether products of the People’s Republic of China are being imported into the United States in such increased quantities or under such conditions as to cause or threaten to cause market disruption to the domestic producers of like or directly competitive products.” The circumstances that mandate the initiation of an investigation include the filing of a petition by an entity, including a trade association, firm, certified or recognized union, or group of workers, which is representative of an industry.

Public Law 106–286, 114 Stat. 880, which added section 421 to the Trade Act, was signed by the President on October 10, 2000. The Commission promulgated interim rules for petitions and investigations under section 421, which are set forth in part 206, subparts A and E, of the Commission’s Rules of Practice and Procedure. See 67 FR 8183

(Feb. 22, 2002) and 67 FR 38614 (June 5, 2002).

The Commission has completed three such investigations to date. See 68 FR 48938 (Aug. 15, 2003), 68 FR 8926 (Feb. 26, 2003), and 67 FR 69557 (Nov. 18, 2002). A fourth investigation is in progress. See 68 FR 54010 (Sept. 15, 2003). Each investigation was initiated in response to a petition. The Commission's experiences with those petitions and investigations have led it to conclude that provisions of the interim rules should be revised without delay.

The Procedure for Adopting the Interim Amendments

The Commission ordinarily promulgates amendments to the Code of Federal Regulations in accordance with the rulemaking procedure in section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). That procedure entails publishing a notice of proposed rulemaking in the **Federal Register** that solicits public comment on the proposed amendments, considering the public comments in deciding on the final content of the amendments, and publishing the final amendments at least 30 days prior to their effective date. In this instance, however, the Commission is amending its rules in 19 CFR part 206 on an interim basis, effective upon publication of this notice in the **Federal Register**.

The Commission's authority to adopt interim amendments without following all steps listed in section 553 of the APA is derived from section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) and section 553 of the APA.

Section 335 of the Tariff Act authorizes the Commission to adopt such reasonable procedures, rules, and regulations as it deems necessary to carry out its functions and duties. The Commission has determined that the need for interim rulemaking is clear in this instance. Section 421 of the Trade Act requires the Commission to evaluate the petition, institute the requested investigation, conduct a hearing, compile an investigative record, and make the required determination(s) in each investigation "at the earliest practicable time" but no later than the prescribed deadline. Rulemaking is essential for orderly administration and compliance with the duties, responsibilities, and deadlines imposed by section 421.

Section 553(b) of the APA allows an agency to dispense with publication of a notice of proposed rulemaking when the following circumstances exist: (1) The rules in question are interpretive rules, general statements of policy, or

rules of agency organization, procedure or practice; or (2) the agency for good cause finds that notice and public comment on the rules are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates that finding and the reasons therefor into the rules adopted by the agency.

In this instance, the Commission has determined that the requisite circumstances exist for dispensing with the notice, comment, and advance publication procedure that ordinarily precedes the adoption of Commission rules. For purposes of invoking the section 553(b) exemption from publishing a notice of proposed rulemaking that solicits public comment, the Commission finds that the interim amendments to part 206 are "agency rules of procedure and practice."

In light of the statutory time constraints for an investigation under section 421(b), the petitioner and the petition must serve as primary sources of information in each investigation based on a petition. The current rules do not require the petition to provide certain information that is critical for the commencement of key investigative activity such as the preparation and issuance of Commission questionnaires and the verification of allegations set forth in the petition. As a result, the issuance of questionnaires and the verification process have been delayed and petitioners have been forced to compile and provide the necessary information on an expedited basis after the petition was filed and the statutory period for completing the investigation had begun to run.

Experience also has shown that there is a need for greater clarity regarding (1) the petitioner's service of public and/or nonconfidential copies of the petition on other parties to the investigation, (2) limitations on the content of written comments filed by parties following submission of their post-hearing briefs, and (3) the closing of the investigative record.

The facts and circumstances described above make it necessary for the Commission to amend the existing rules without delay. Hence, it would be impracticable for the Commission to publish a notice of proposed rulemaking, and to consider any comments received in response to the notice, prior to making the necessary rule changes.

Section 553(d)(3) of the APA allows an agency to dispense with the publication of notice of final rules at least thirty days prior to their effective date if the agency finds that good cause exists for not meeting the advance

publication requirement and the agency publishes that finding along with the rules. The Commission finds that the facts and circumstances described above also constitute good cause for the purpose of invoking that exemption.

The Commission recognizes that interim amendments to the rules should not respond to anything more than the exigencies created by the aforesaid facts and circumstances. Each amendment set forth in this notice accordingly does one or more of the following: (1) Addresses a concern regarding the existing rule specifying the required content of a petition under section 421(b) of the Trade Act; (2) provides clarity about the petitioner's obligation to serve copies of the petition on other parties to the investigation, the appropriate content of written comments filed after submission of the post-hearing briefs, and the closing of the investigative record; or (3) resolves a matter not adequately addressed in the current rules, such as the deadline for the petitioner to serve copies of the petition on other parties to the investigation following notification by the Secretary to the Commission of acceptance of an administrative protective order application or issuance of a service list and amendment thereto.

The Commission will replace the interim rules in part 206 with final rules promulgated in accordance with the notice, comment, and advance publication procedure prescribed in section 553 of the APA after taking into account (1) all comments received in response to the interim rules as originally adopted (see 67 FR 8183), (2) any comments received in response to the amendments set forth in this notice, and (3) the experience acquired in all investigations under section 421(b) that are conducted prior to commencement of the APA procedure for final rulemaking.

Section-by-Section Analysis of the Interim Amendments

Section 206.44

Paragraphs (a)–(i) of section 206.44 list the required content of a petition for an investigation under section 421(b)(1) of the Act. The Commission amends section 206.44 by making substantive and/or technical revisions to existing paragraphs (a), (c), (j), and (i) and adding a new paragraph (j).

Paragraph (a). Paragraph (a) of section 206.44 imposes the basic requirement that the petition must provide specific information to support the claim that products of the People's Republic of China are being imported into the United States in such increased quantities or under such conditions as

to cause or threaten to cause market disruption to the domestic producers of like or directly competitive products. Paragraph (a) also states that each petition should provide the information specified in paragraphs (a) through (i)—*i.e.*, a product description and information about representativeness, imports, domestic production, injury or threat of injury, cause of injury, critical circumstances, the relief sought and the purpose thereof—to the extent that such information is reasonably available to the petitioner with due diligence.

The Commission redesignates the current paragraph (a) as paragraph (a)(1). The Commission adds a new paragraph (a)(2) that requires an additional certification if the petition fails to include any data or information that is required by a provision of section 206.44 that applies to a petition for an investigation under section 421(b)(1) of the Act. In such a case, the new paragraph (a)(2) will require the petition to include a certification that the missing information was not reasonably available to the petitioner. The Commission intends for the additional certification to impress upon each petitioner the importance of exercising due diligence to compile and submit the information specified in section 206.44 to the extent that the information is reasonably available to the petitioner.

The Commission also amends paragraph (a) of section 206.44 to make technical revisions. Paragraph (a) contains two references to “paragraphs (b)–(i).” Because the Commission is adding a new paragraph (j) to section 206.44 (as discussed below), the Commission changes the reference from “paragraphs (b)–(i)” to “paragraphs (b)–(j).”

Paragraph (c). A petition for an investigation under section 421(b)(1) of the Act must be filed by an entity described in 19 U.S.C. 2252(a)—that is, an entity, including a trade association, firm, certified or recognized union, or group of workers, which is representative of an industry. To enable the investigative staff to promptly verify the information that the petition provides to comply with paragraph (c) of section 206.44, the Commission revises paragraph (c)(1) to require the petition to include the name and telephone number of a contact person for each producer that is represented in the petition or that employs or previously employed workers represented in the petition. The Commission also revises paragraph (c)(3) to require the petition to provide the name and telephone number of a contact person for each other producer of the domestic product known to the

petitioner. Requiring the aforesaid information to be set forth in the petition will expedite the Commission’s gathering of information and relieve the petitioner from having to provide it on an expedited basis after the petition is filed.

New Paragraph (j). Much of the information that will be critical in helping the Commission make the required determination(s) in an investigation under section 421(b)(1) of the Trade Act is obtained from responses to Commission questionnaires. The Commission seeks to issue the questionnaires as expeditiously as possible. However, Commission staff cannot complete the drafting of questionnaires or mail them until it has compiled certain information about the subject products and the names and addresses of domestic and foreign producers, importers, and purchasers believed to have information relevant to the investigation. Section 206.44 does not currently require the petition to provide such information.

The Commission accordingly adds a new paragraph (j) to section 206.44. Paragraph (j)(1) requires the petition to include the name, address, and telephone number of each U.S. importer and producer in China of the products under investigation. Paragraph (j)(3) requires the petition to furnish the name, address, primary contact person, and telephone number for each of the 10 largest purchasers of each domestic producer represented in, or that employs or formerly employed workers represented in, the petition. The Commission believes that the information required by paragraphs (j)(1) and (j)(3) should be readily available to petitioner(s) from its (their) own records, public sources, or other sources.

New paragraph (j) of section 206.44 includes a paragraph (j)(2) that requires the petition to provide a detailed description of each product for which the petitioner wants the Commission to seek pricing information in its questionnaires and an explanation of why the petitioner believes the Commission should collect pricing information for that product.

The Commission believes that having the information specified in paragraphs (j)(1), (j)(2), and (j)(3) should enable the investigative staff to prepare and mail the Commission questionnaires sooner—which, in turn, would give the recipients more time to respond and give the staff, the Commission, and authorized representatives of parties to the investigation more time to evaluate the responses.

The new paragraph (j) also includes a paragraph (j)(4) that requires the petition to furnish information to support each allegation of a lost sale or lost revenue. The required supporting information includes the date, value, and product quantity of each such alleged loss. It also includes the name of the company that lost the sale, the name of the customer involved, and the name of the company that captured the sale or whose competition resulted in the lost revenue, and company addresses, contact persons, and telephone numbers. The Commission believes that requiring the petition to provide such information will facilitate staff verification of the allegation and will relieve the petitioner of the burden of having to furnish the information on an expedited basis after the petition is filed.

Current Paragraph (j). Having amended section 206.44 by adding a new paragraph (j) as discussed above, the Commission redesignates the current paragraph (j) as paragraph (k).

The Creation of a New Section 206.44a

The Commission further amends Part 206 of its Rules of Practice and Procedure by adding a new section 206.44a to establish special rules for investigations under section 421(b) of the Trade Act.

Paragraph (a) of the new section 206.44a addresses the petitioner’s obligation to serve confidential and/or public copies of the petition on other parties to the investigation and provides for earlier service of the petition. The Commission intends for paragraph (a) to provide clarity about a matter not adequately addressed in the current rules, namely the deadline for the petitioner to serve copies of the petition on other parties to the investigation following notification by the Secretary of approval of an application for disclosure under an administrative protective order, before establishment of a service list; the deadline for such service upon notification of the establishment of a service list; and the deadline for such service upon notification of an amendment of the service list.

Paragraph (b) of the new section 206.44a addresses the submission of written comments by parties after submission of their post-hearing briefs. The Commission adopts this paragraph to provide greater clarity on the issue of when the record closes. The Commission also intends for paragraph (b) to have the effect of preventing the recurrence of a problem that occurred in a recently completed investigation, namely, a party’s inclusion of new

information in written comments submitted after the post-hearing briefs were filed. Paragraph (b) is similar to section 207.30(b) of the Commission's Rules of Practice and Procedure (19 CFR 207.30(b)), which governs parties' written comments on new information during the final phase of a countervailing duty investigation or an antidumping duty investigation under Title VII of the Tariff Act of 1930. The Commission intends for paragraph (b) of the new section 206.44a to make it clear that a party to an investigation under section 421(b) of the Trade Act should not include new information in comments filed after the submission of its post-hearing brief, unless the Commission grants the party leave to do so.

Regulatory Analysis

The Regulatory Flexibility Act

The Commission notes that the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of proposed rulemaking is required under section 553(b) of the APA. (See the discussion above concerning the procedure for adopting the interim amendments.)

Even if the Regulatory Flexibility Act applied, the Commission's interim amendments to part 206 are not likely to affect small entities in the manner that the Act is intended to prevent. The interim amendments are agency rules of procedure and practice. Some procedures codified in the amendments are the same as or substantially similar to procedures codified in existing rules for other types of investigations. Moreover, the Commission has no reason to believe, at this point, that a large number of the petitioners will be small entities. For those reasons, the Commission certifies, pursuant to 5 U.S.C. 605(b), that the interim rule amendments in this notice will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

The Commission has determined that the interim amendments to part 206 do not meet the criteria described in section 3(f) of Executive Order 12866 (58 FR 51735, Oct. 4, 1993) and thus do not constitute a significant regulatory action for purposes of the Executive Order. As noted, they merely respond to exigencies created by the statutory time constraints and concerns created by the existing rules. The interim amendments to part 206 will not result in (1) an annual effect on the economy of \$100 million or more, (2) a major increase in

costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, or (3) 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 foreign markets. Accordingly, no regulatory impact assessment is required.

Executive Order 13132

The interim amendments to part 206 of the Commission's rules do not contain federalism implications warranting the preparation of a Federalism Assessment pursuant to Executive Order 13132 (64 FR 43255, Aug. 4, 1999).

The Unfunded Mandates Reform Act of 1995

The interim amendments to part 206 of the Commission's rules will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*).

The Small Business Regulatory Enforcement Fairness Act of 1996

The interim amendments to part 206 of the Commission's rules are not major rules as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). The interim amendments will not result in an annual effect on the economy of \$100,000,000 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.

The Contract With America Advancement Act of 1996

The interim amendments to part 206 of the Commission's rules are exempt from the reporting requirements of the Contract With America Advancement Act of 1996 (Pub. L. 104-121) because they concern rules of agency procedure or practice that do not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 19 CFR Part 206

Administrative practice and procedure, investigations.

■ For the reasons stated in the preamble, the Commission amends 19 CFR part 206 as follows:

PART 206—INVESTIGATIONS RELATING TO GLOBAL AND BILATERAL SAFEGUARD ACTIONS, MARKET DISRUPTION, AND REVIEW OF RELIEF ACTIONS

■ 1. The authority citation for part 206 continues to read as follows:

Authority: 19 U.S.C. 1335, 2251–2254, 2451–2451a, 3351–3382; secs. 103, 301–302, Pub. L. 103–465, 108 Stat. 4809.

■ 2. Amend § 206.44 by revising paragraph (a), revising paragraphs (c)(1) and (c)(3), re-designating paragraph (j) as paragraph (k), and adding a new paragraph (j), to read as follows:

§ 206.44 Contents of a petition under section 421(b) or (o) of the Trade Act.

(a) *Petitions under section 421(b).* (1) A petition for relief under section 421(b) of the Trade Act shall provide specific information in support of the claim that products of the People's Republic of China are being imported into the United States in such increased quantities or under such conditions as to cause or threaten to cause market disruption to the domestic producers of like or directly competitive products. In addition, such petition shall include the information described in paragraphs (b) through (j) of this section. The petition shall provide the information required by this paragraph and paragraphs (b) through (j) of this section to the extent that such information is reasonably available to the petitioner with due diligence.

(2) If the petition fails to provide any item of information specified in paragraphs (b) through (j) of this section, the petition shall include a certification that such information was not reasonably available to the petitioner.

* * * * *

(c) *Representativeness.* Each petition shall include:

(1) The names and street addresses of the firms represented in the petition and/or the firms employing or previously employing the workers represented in the petition, the locations of the establishments in which each such firm produces the domestic product, and the telephone number and contact person(s) for each such firm;

* * * * *

(3) The names and street addresses of all other producers of the domestic product known to the petitioner, and

the telephone number and contact person(s) for each such producer.

(j) *Additional information.* The petition shall include:

(1) The names of all U.S. importers and all producers in China of the subject merchandise known to petitioner, and the street address, telephone and fax number, and primary contact person(s) for each such importer and producer in China;

(2) A detailed description of each product for which the petitioner requests the Commission to seek pricing information in its questionnaires, and an explanation of why the petitioner believes the Commission should collect pricing information for each such product;

(3) For each domestic producer represented by petitioner, the company names of its 10 largest purchasers, and the street address, telephone number, and primary contact person(s) for each such purchaser;

(4) For each allegation of lost sales and/or lost revenues, supporting information with regard to each such alleged loss, including the name of the company represented by petitioner that lost the sale or revenue, the name of the company that captured the sale or whose competition resulted in lost revenue (including company street address, company contact person, and telephone and fax numbers for each contact person), the date and total value of the lost sale or lost revenue, and the total quantity of product involved (by weight or number of units).

(k) *Petitions under section 421(o).*

* * * * *

■ 2. Amend part 206 by adding § 206.44a to read as follows:

§ 206.44a Special rules for conducting investigations under section 421(b) of the Trade Act.

(a) *Service of the petition.* (1)(i) The Secretary shall promptly notify a petitioner when, before the establishment of a service list under § 206.17(a)(4) of this part, he or she approves an application under § 206.17(a)(2) of this part pursuant to § 206.47. When practicable, this notification shall be made by facsimile transmission. The petitioner shall then serve a copy of the petition, including all confidential business information, on the approved lead authorized applicants in accord with § 206.17(f) within 2 calendar days of the time notification is made by the Secretary.

(ii) Upon establishment and issuance of the service list, the petitioner shall serve the lead authorized applicants enumerated on the list established by the Secretary pursuant to § 206.17(a)(4)

that have not been served pursuant to paragraph (a)(1)(i) of this section within 2 calendar days of the establishment and issuance of the Secretary's list.

(2) As the Secretary adds new authorized applicants to the service list described in paragraph (a)(1) of this section, the Secretary shall notify the petitioner and issue an amended list, and the petitioner shall serve new lead authorized applicants with a copy of the petition in the same manner as under paragraph (a)(1)(i) of this section.

(3) The petitioner shall serve a copy of the non-confidential version of the petition on those persons enumerated on the list established by the Secretary pursuant to § 201.11(d) of this chapter within 2 calendar days of the establishment and issuance of the Secretary's list, and on any additional persons within 2 calendar days of receiving notification from the Secretary of an amended list.

(4) The petitioner shall attest service of the petition by filing a certificate of service with the Commission.

(b) *Comment on information.* The parties shall have an opportunity to file comments on any information disclosed to them after they have filed their posthearing brief. Comments shall concern only such information, and shall not exceed 15 pages of textual material, double-spaced and on single-sided stationery measuring 8½ x 11 inches. A comment may address the accuracy, reliability, or probative value of such information by reference to information elsewhere in the record, in which case the comment shall identify where in the record such information is found. New factual information and arguments based on that information shall be disregarded. The date on which such comments must be filed will be specified by the Commission when it specifies the time that information will be disclosed. The record shall close on the date such comments are due, except with respect to changes in bracketing of confidential business information permitted by § 206.8(c) of this part.

Issued: November 13, 2003.

By Order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 03-28879 Filed 11-18-03; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dexamethasone 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 an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for the veterinary prescription use of dexamethasone injectable solution in dogs, cats, cattle, and horses.

DATES: This rule is effective November 19, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-312 that provides for use of DEXIUM (dexamethasone) Solution for the treatment of primary bovine ketosis and as an anti-inflammatory agent in dogs, cats, cattle, and horses. Cross Vetpharm Group's DEXIUM Solution is approved as a generic copy of Schering-Plough Animal Health's AZIUM Solution 2 milligrams, approved under NADA 12-559. The ANADA is approved as of October 20, 2003, and the regulations are amended in 21 CFR 522.540 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 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 Division of Dockets Management (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.

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