

B. Executive Order 12866: Regulatory Impact

This proposed rule has been determined to be not significant within the meaning of Executive Order 12866.

C. Executive Order 13132: Federalism Assessment

NOAA has concluded this regulatory action does not have federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132.

D. Paperwork Reduction Act

This rule does not contain any new or revisions to the existing information collection requirement that was approved by OMB (OMB Control Number 0648-0141) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

E. Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification was published with the proposed rule and is not repeated here. No comments were received regarding the economic impact of this rule. As a result, a final regulatory flexibility analysis was not prepared.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Environmental protection, Fish, Harbors, Marine pollution, Marine resources, Natural resources, Penalties, Recreation and recreation areas, Research, Water pollution control, Water resources, Wildlife, Overflights.

Dated: January 20, 2012.

Holly A. Bamford,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, 15 CFR part 922 is amended as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

■ 1. The authority citation for part 922 continues to read as follows:

Authority: 15 U.S.C. 1431 *et seq.*

Subpart G—Channel Islands National Marine Sanctuary

■ 2. Amend § 922.72 by revising paragraph (a)(7) to read as follows:

§ 922.72 Prohibited or otherwise regulated activities—Sanctuary-wide.

(a) * * *

(7) Disturbing marine mammals or seabirds by flying motorized aircraft at less than 1,000 feet over the waters within one nautical mile of any Island, except to engage in kelp bed surveys or to transport persons or supplies to or from an Island. Failure to maintain a minimum altitude of 1,000 feet above ground level over such waters is presumed to disturb marine mammals or seabirds.

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Subpart H—Gulf of Farallones National Marine Sanctuary

■ 3. Amend § 922.82 by revising paragraph (a)(8) to read as follows:

§ 922.82 Prohibited or otherwise regulated activities.

(a) * * *

(8) Disturbing marine mammals or seabirds by flying motorized aircraft at less than 1,000 feet over the waters within one nautical mile of the Farallon Islands, Bolinas Lagoon, or any ASBS, except to transport persons or supplies to or from the Islands or for enforcement purposes. Failure to maintain a minimum altitude of 1,000 feet above ground level over such waters is presumed to disturb marine mammals or seabirds.

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Subpart M—Monterey Bay National Marine Sanctuary

■ 4. Amend § 922.132 by revising paragraph (a)(6) to read as follows:

§ 922.132 Prohibited or otherwise regulated activities.

(a) * * *

(6) Disturbing marine mammals or seabirds by flying motorized aircraft, except as necessary for valid law enforcement purposes, at less than 1,000 feet above any of the four zones within the Sanctuary described in Appendix B to this subpart. Failure to maintain a minimum altitude of 1,000 feet above ground level above any such zone is presumed to disturb marine mammals or seabirds.

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Subpart O—Olympic Coast National Marine Sanctuary

■ 5. Amend § 922.152 by revising paragraph (a)(7) to read as follows:

§ 922.152 Prohibited or otherwise regulated activities.

(a) * * *

(7) Disturbing marine mammals or seabirds by flying motorized aircraft at less than 2,000 feet over the waters within one nautical mile of the Flattery Rocks, Quillayute Needles, or Copalis National Wildlife Refuges or within one nautical mile seaward from the coastal boundary of the Sanctuary, except for activities related to tribal timber operations conducted on reservation lands, or to transport persons or supplies to or from reservation lands as authorized by a governing body of an Indian tribe. Failure to maintain a minimum altitude of 2,000 feet above ground level over any such waters is presumed to disturb marine mammals or seabirds.

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INTERNATIONAL TRADE COMMISSION

19 CFR Part 206

Rules for Investigations Relating to Global and Bilateral Safeguards Actions, Market Disruption, Trade Diversion, and Review of Relief Actions

AGENCY: United States International Trade Commission.

ACTION: Interim rule with request for comments.

SUMMARY: The United States International Trade Commission (Commission) is adopting interim rules that amend the Commission's Rules of Practice and Procedure to make technical amendments and to provide rules for the conduct of safeguard investigations under statutory provisions that implement bilateral safeguard provisions in free trade agreements that the United States has negotiated with Australia, Bahrain, Chile, Colombia, the Dominican Republic and five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua), Jordan, Korea, Morocco, Oman, Panama, Peru, and Singapore. With the exception of the free trade agreements with Colombia, Korea, and Panama, all of the aforementioned free trade agreements have entered into force. The free trade

agreements with Colombia, Korea, and Panama are expected to enter into force imminently. The interim rules would amend and expand upon current rules that pertain to the conduct of bilateral safeguard investigations under the North American Free Trade Agreement (NAFTA) Implementation Act with respect to imports from Canada and Mexico.

DATES: *Effective date:* January 26, 2012.

Deadline for filing written comments: March 26, 2012.

ADDRESSES: You may submit comments, identified by docket number MISC-039, FTA safeguards rulemaking, by any of the following methods:

—*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

—*Agency Web Site:* <http://edis.usitc.gov>. Follow the instructions for submitting comments on the Web site.

—*Mail:* For paper submission. U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436.

—*Hand Delivery/Courier:* U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436. From the hours of 8:45 a.m. to 5:15 p.m.

Instructions: All submissions received must include the agency name and docket number (MISC-039, FTA safeguards rulemaking), along with a cover letter stating the nature of the commenter's interest in the proposed rulemaking. All comments received will be posted without change to <http://edis.usitc.gov> including any personal information provided. For paper copies, a signed original and 8 copies of each set of comments should be submitted to James R. Holbein, Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436. For access to the docket to read background documents or comments received, go to <https://edis.usitc.gov> and/or the U.S. International Trade Commission, 500 E Street SW., Room 112A, Washington, DC 20436.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary, telephone (202) 205-2000 or William Gearhart, Esquire, Office of the General Counsel, United States International Trade Commission, telephone (202) 205-3091. Hearing-impaired individuals 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 may also be obtained by accessing its Web site at <http://www.usitc.gov>.

SUPPLEMENTARY INFORMATION: The preamble below is designed to assist readers in understanding these amendments to the Commission Rules. This preamble provides background information, a regulatory analysis of the amendments, a section-by-section explanation of the amendments, and a description of the amendments to the Rules. The Commission encourages members of the public to comment, in addition to any other comments they wish to make on the amendments, on whether the amendments are in language that is sufficiently clear for users to understand.

These amendments are being promulgated in accordance with the Administrative Procedure Act (5 U.S.C. 553) (APA), and will be codified in 19 CFR part 206.

Background

Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) authorizes the Commission to adopt such reasonable procedures, rules and regulations as it deems necessary to carry out its functions and duties. The Commission is amending its rules governing investigations relating to global and bilateral safeguard actions, market disruption, trade diversion and review of relief actions (Part 206 of its Rules). The amendments principally concern Subpart D of Part 206, Investigations Relating to Bilateral Safeguard Actions, but also include several technical and conforming changes to the general rules in Subpart A of Part 206. The current rules in Subpart D apply only to Commission investigations under the bilateral safeguard provision in the NAFTA Implementation Act with respect to imports from Canada and Mexico. However, in recent years Congress has enacted legislation that implements bilateral safeguard provisions in several additional free trade agreements, including most recently agreements with Colombia, Korea, and Panama. The implementing legislation for each of those free trade agreements directs the Commission, upon receipt of a petition, to conduct an investigation and determine whether, as a result of the reduction or elimination of a duty under the agreement, an article is being imported into the United States in such increased quantities, in absolute terms or relative to domestic production, and under such conditions that imports of such article constitute a substantial cause of serious injury or the threat thereof to the domestic industry producing an article that is like or directly competitive with the imported article. If the Commission makes an affirmative determination, it must

recommend a remedy to the President; the President makes the final decision on remedy.

In addition to the NAFTA Implementation Act, the Commission is required to conduct bilateral safeguard investigations and make determinations under section 311(b) of the United States-Australia Free Trade Agreement Implementation Act, section 311(b) of the United States-Bahrain Free Trade Agreement Implementation Act, section 311(b) of the United States-Chile Free Trade Agreement Implementation Act, section 311(b) of the United States-Colombia Trade Promotion Agreement Implementation Act, section 311(b) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act, section 211(b) of the United States-Jordan Free Trade Area Implementation Act, section 311(b) of the United States-Korea Free Trade Agreement Implementation Act, section 311(b) of the United States-Morocco Free Trade Agreement Implementation Act, section 311(b) of the United States-Oman Free Trade Agreement Implementation Act, section 311(b) of the United States-Panama Trade Promotion Agreement Implementation Act, section 311(b) of the United States-Peru Trade Promotion Agreement Implementation Act, and section 311(b) of the United States-Singapore Free Trade Agreement Implementation Act (for U.S. Code citations to the respective implementation acts, see the text of interim rule section 206.31 *infra*).

These amendments expand upon existing rules in Subpart D of Part 206 that provide for investigations and determinations under the NAFTA Implementation Act. Each of the statutory provisions listed above contains requirements that are similar both substantively and procedurally to the provision in the NAFTA Implementation Act. These amended rules identify the types of entities that may file a petition, describe the information that must be included in a petition, indicate the time for Commission determinations and reporting, and establish procedures for the limited disclosure of confidential business information under administrative protective order in those instances in which the Commission is authorized to make such disclosure.

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 rules is clear in this instance. Recently enacted legislation that implements safeguard provisions in free trade agreements, including agreements with Colombia, Korea, and Panama, requires the Commission to conduct new kinds of investigations and make determinations. It is important that the Commission adopt implementing rules as quickly as possible because the three new agreements are expected to enter into force imminently. The interim amendments will also apply in the case of investigations under legislation that implements safeguard provisions in free trade agreements that have already entered into force with respect to the other countries listed above. In light of the similarity of the provisions in the various implementing statutes, the Commission did not view it as practical to issue a notice of interim rulemaking applicable to investigations involving goods from one or several free trade agreement partners and at the same time issue a substantially identical notice of proposed rulemaking applicable to investigations involving goods from other free trade agreement partners. These interim rules will apply to investigations and determinations under a particular free trade agreement implementation act only after the relevant agreement has entered into force.

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.

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.

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." Moreover, the entry into force of the new agreements, particularly the agreement with Korea, which applies to a significant amount of U.S. import trade and which could not be predicted sufficiently far in advance, makes the establishment of rules a matter of urgency. Hence, it clearly would have been impracticable for the Commission to comply with the notice of proposed rulemaking and public comment procedure.

For the purpose of invoking the section 553(d)(3) exemption from publishing advance notice of the interim amendments to Part 206 at least thirty days prior to their effective date, the Commission finds the fact that the implementing legislation was signed by the President on October 21, 2011, makes such advance publication impracticable and constitutes good cause for not complying with that requirement.

The Commission recognizes that interim rule amendments should not respond to anything more than the exigencies created by the new legislation. Each interim amendment to Part 206 accordingly falls into one or more of the following categories: (1) A revision of a preexisting rule to make it applicable to one or more of the new kinds of investigations of relief actions; (2) clarification of the manner in which a preexisting rule is to be applied to one or more of the new kinds of investigations; or (3) a new rule covering a matter addressed in the new

legislation but not covered by a preexisting rule.

After taking into account all comments received and the experience acquired under the interim amendments, the Commission will replace them with final amendments promulgated in accordance with the notice, comment, and advance publication procedure prescribed in section 553 of the APA.

Regulatory Analysis of Proposed Amendments to the Commission's Rules

The Commission has determined that the proposed rules do not meet the criteria described in section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993) and thus do not constitute a significant regulatory action for purposes of the Executive Order.

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 final rulemaking is required under 5 U.S.C. 553(b) or any other statute.

These interim rules do not contain federalism implications warranting the preparation of a federalism summary impact statement pursuant to Executive Order 13132 (64 FR 43255, August 4, 1999).

No actions are necessary under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) because the interim 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.

The interim rules are not major rules as defined by section 804 of the Congressional Review Act (5 U.S.C. 801 *et seq.*). Moreover, they are exempt from the reporting requirements of that Act because they contain rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

The amendments are not subject to section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), since they do not contain any new information collection requirements.

Section-by-Section Explanation of the Proposed Amendments

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

Section 206.1 of subpart 206, which lists the statutory authorities and investigations to which subpart 206

applies, is being amended to add a reference to the list of the statutory authorities that are being added in Subpart D of subpart 206 under which the Commission may conduct a bilateral FTA safeguard investigation. Section 206.1 is being further amended to delete the cross references between statutory authorities and part 206 subparts. This information is readily apparent either from the title of the subpart or the first section in each subpart, which lists the statutory authorities and investigations to which the subpart applies.

Subpart A of Part 206 sets forth rules of general application for Commission safeguard investigations. This subpart is being amended in two principal respects. Section 206.2 is amended to extend to entities filing petitions under bilateral safeguard provisions the requirement that the petitioning entity identify the statutory authority and rule subpart under which the petition is filed. Section 206.6(a)(2) is amended to state that the Commission, if it makes an affirmative determination or is equally divided in its determination, will include in its report such remedy recommendations or proposals as may be appropriate under the statute and an explanation of the basis for each recommendation or proposal. The amendment deletes a reference to a statutory provision that applies only in certain market disruption investigations.

Subpart D of Part 206 is amended to apply to Commission investigations under several statutory authorities that implement FTA safeguard provisions. As amended, Subpart D is divided into seven sections. Section 206.31 lists the statutory authorities under which the Commission conducts such investigations. Section 206.32 sets forth definitions for terms applicable to some or all such investigations, including “substantial cause,” “domestic industry,” “critical circumstances,” “perishable agricultural product,” and “Korean motor vehicle article.” The definitions of “substantial cause,” “domestic industry,” and “Korean motor vehicle article” are not in the current rule; however, they reflect statutory definitions.

Section 206.33(a) lists the types of entities that may file a petition. The list is the same as in the current rule, but the rule is revised to refer to the list of statutory authorities in section 206.31. Current section 206.33(b) is redesignated as section 206.33(d) and is amended to list the countries whose goods might be the subject of a request for provisional relief with respect to a perishable agricultural product. New section 206.33(b) lists the agreements for which U.S. implementing legislation

has been enacted that provides for the subject Commission investigations. Current section 206.33(c) is deleted and is replaced by a new section 206.33(c) that relates to allegations of critical circumstances and lists the FTA countries whose goods might be the subject of a request for provisional relief when critical circumstances are alleged. The Commission is deleting current section 206.33(c), which describes the President’s authority to provide relief after expiration of the transition period in NAFTA cases, because it finds it impractical and unnecessary to describe more generally the President’s authority under the various free trade agreement implementing statutes.

Section 206.34 describes the information that must be included in a petition filed under Subpart D. The information required is similar to that in current section 206.34 for petitions filed under the NAFTA safeguard provisions. Like the current rule, the amended rule recognizes that not all of the requested information may be available to the entity seeking to file a petition. Accordingly, the amended rule directs that the entity provide the requested information to the extent that such information is publicly available from governmental or other sources, or best estimates and the basis therefor if such information is not available.

Section 206.35 sets forth the time period that the Commission has to make its injury determination and transmit its report after an investigation is initiated, and also indicates the time period for making and reporting determinations when provisional relief is requested. These time periods are the same as in the implementing statutes.

Section 206.36, which states that the Commission will make its reports available to the public (with the exception of confidential business information) and will publish a summary in the **Federal Register**, is not changed.

New section 206.37 is added to provide for limited disclosure of certain confidential business information under administrative protective order in investigations under implementing statutes that authorize such disclosure. With the exception of the implementing statutes for the NAFTA and the Jordan FTA, each of the implementing statutes listed in section 206.31 provides for such disclosure.

List of Subjects in 19 CFR Part 206

Administrative practice and procedure, Australia, Bahrain, Business and industry, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras,

Imports, Investigations, Jordan, Korea, Mexico, Morocco, Nicaragua, Oman, Panama, Peru, Singapore, Trade agreements.

For the reasons stated in the preamble, the United States International Trade Commission amends 19 CFR Part 206 as follows:

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

- 1. Revise the authority citation for part 206 to read as follows:

Authority: 19 U.S.C. 1335, 2112 note, 2251–2254, 2436, 2451–2451a, 3351–3382, 3805 note, 4051–4065, and 4101.

- 2. Revise § 206.1 to read as follows:

§ 206.1 Applicability of part.

Part 206 applies to proceedings of the Commission under 201–202, 204, 406, and 421–422 of the Trade Act of 1974, as amended (2251–2252, 2254, 2436, 2451–2451a), sections 301–317 of the North American Free Trade Agreement Implementation Act (19 U.S.C. 3351–3382) (hereinafter NAFTA Implementation Act), and the statutory provisions listed in section 206.31 of this part 206 that implement bilateral safeguard provisions in other free trade agreements into which the United States has entered.

- 3. Revise § 206.2 to read as follows:

§ 206.2 Identification of type of petition or request.

An investigation under this part 206 may be commenced on the basis of a petition, request, resolution, or motion as provided for in the statutory provisions listed in §§ 206.1 and 206.31. Each petition or request, as the case may be, filed by an entity representative of a domestic industry under this part 206 shall state clearly on the first page thereof “This is a [petition or request] under section [citing the statutory provision] and Subpart [B, C, D, E, F, or G] of part 206 of the rules of practice and procedure of the United States International Trade Commission.”

- 4. Amend § 206.6 by revising paragraph (a)(2) to read as follows:

§ 206.6 Report to the President.

(a) * * *

(2) If the determination is affirmative or if the Commission is equally divided in its determination, such remedy recommendation or proposal as may be appropriate under the statute and an

explanation of the basis for each recommendation or proposal.

* * * * *

■ 5. Revise § 206.31 to read as follows:

§ 206.31 Applicability of subpart.

This subpart D applies specifically to investigations under section 311(b) of the United States-Australia Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Bahrain Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Chile Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Colombia Trade Promotion Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (19 U.S.C. 4061(b)), section 211(b) of the United States-Jordan Free Trade Area Implementation Act (19 U.S.C. 2112 note), section 311(b) of the United States-Korea Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Morocco Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 302(b) of the NAFTA Implementation Act (19 U.S.C. 3352(b)), section 311(b) of the United States-Oman Free Trade Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Panama Trade Promotion Agreement Implementation Act (19 U.S.C. 3805 note), section 311(b) of the United States-Peru Trade Promotion Agreement Implementation Act (19 U.S.C. 3805 note), and section 311(b) of the United States-Singapore Free Trade Agreement Implementation Act (19 U.S.C. 3805 note). For other applicable rules, see subpart A of this part and part 201 of this chapter.

■ 6. Revise § 206.32 to read as follows:

§ 206.32 Definitions applicable to subpart D.

For the purposes of this subpart, the following terms have the meanings hereby assigned to them:

(a) The term *substantial cause* has the same meaning as section 202(b)(1)(B) of the Trade Act.

(b) The terms *domestic industry*, *serious injury*, and *threat of serious injury* have the same meanings as in section 202(c)(6) of the Trade Act.

(c) *Critical circumstances* mean such circumstances as are described in section 202(d) of the Trade Act;

(d) *Perishable agricultural product* means any agricultural product or citrus product, including livestock, which is

the subject of monitoring pursuant to section 202(d) of the Trade Act.

(e) *Korean motor vehicle article* means a good provided for in heading 8703 or 8704 of the U.S. Harmonized Tariff Schedule that qualifies as an originating good under section 202(b) of the United States-Korea Free Trade Agreement Implementation Act.

■ 7. Revise § 206.33 to read as follows:

§ 206.33 Who may file a petition.

(a) *In general.* A petition under this subpart D may be filed by an entity, including a trade association, firm, certified or recognized union, or group of workers, that is representative of a domestic industry producing an article that is like or directly competitive with an article that is allegedly, as a result of the reduction or elimination of a duty provided for under a free trade agreement listed in paragraph (b) of this section, being imported into the United States in such increased quantities, in absolute terms or relative to domestic production, and under such conditions that imports of the article constitute a substantial cause of serious injury, or (except in the case of a Canadian article) threat thereof, to such domestic industry. Unless the implementation statute provides otherwise, a petition may be filed only during the transition period of the particular free trade agreement.

(b) *List of free trade agreements.* The free trade agreements referred to in paragraph (a) of this section include the United States-Australia Free Trade Agreement, the United States-Bahrain Free Trade Agreement, the United States-Chile Free Trade Agreement, the United States-Colombia Trade Promotion Agreement, the Dominican Republic-Central America-United States Free Trade Agreement, the United States-Jordan Free Trade Area Agreement, the United States-Korea Free Trade Agreement, the United States-Morocco Free Trade Agreement, the North American Free Trade Agreement (NAFTA), the United States-Oman Free Trade Agreement, the United States-Panama Trade Promotion Agreement, the United States-Peru Trade Promotion Agreement, and the United States-Singapore Free Trade Agreement, to the extent that such agreements have entered into force.

(c) *Critical circumstances.* An entity of the type described in paragraph (a) of this section that represents a domestic industry may allege that critical circumstances exist and petition for provisional relief with respect to imports if such product is from Australia, Canada, Jordan, Korea, Mexico, Morocco, or Singapore.

(d) *Perishable agricultural product.*

An entity of the type described in paragraph (a) of this section that represents a domestic industry producing a perishable agricultural product may petition for provisional relief with respect to imports of such product from Australia, Canada, Jordan, Korea, Mexico, Morocco, or Singapore, but only if such product has been subject to monitoring by the Commission for not less than 90 days as of the date the allegation of injury is included in the petition.

(e) *Korean motor vehicle article.* An entity of the type described in paragraph (a) of this section that is filing a petition with respect to a product from Korea shall state whether it represents a domestic industry producing an article that is like or directly competitive with a Korean motor vehicle article.

■ 8. Revise § 206.34 to read as follows:

§ 206.34 Contents of petition.

A petition under this subpart D shall include specific information in support of the claim that, as a result of the reduction or elimination of a duty provided for under a free trade agreement listed in § 206.33(b), an article is being imported into the United States in such increased quantities, in absolute terms or relative to domestic production, and under such conditions that imports of the article constitute a substantial cause of serious injury, or (except in the case of a Canadian article) threat thereof, to the domestic industry producing an article that is like or directly competitive with the imported article. If provisional relief is requested in a petition concerning an article from Australia, Canada, Jordan, Korea, Mexico, Morocco, or Singapore, the petition shall state whether provisional relief is sought because *critical circumstances* exist or because the imported article is a *perishable agricultural product*. In addition, a petition filed under this subpart D shall include the following information, to the extent that such information is publicly available from governmental or other sources, or best estimates and the basis therefor if such information is not available:

(a) *Product description.* The name and description of the imported article concerned, specifying the United States tariff provision under which such article is classified and the current tariff treatment thereof, and the name and description of the like or directly competitive domestic article concerned;

(b) *Representativeness.*

(1) The names and addresses of the firms represented in the petition and/or the firms employing or previously

employing the workers represented in the petition and the locations of their establishments in which the domestic article is produced;

(2) The percentage of domestic production of the like or directly competitive domestic article that such represented firms and/or workers account for and the basis for claiming that such firms and/or workers are representative of an industry; and

(3) The names and locations of all other producers of the domestic article known to the petitioner;

(c) *Import data.* Import data for at least each of the most recent 5 full years that form the basis of the claim that the article concerned is being imported in increased quantities in absolute terms;

(d) *Domestic production data.* Data on total U.S. production of the domestic article for each full year for which data are provided pursuant to paragraph (c) of this section;

(e) *Data showing injury.* Quantitative data for each of the most recent 5 full years indicating the nature and extent of injury to the domestic industry concerned:

(1) With respect to serious injury, data indicating:

(i) A significant idling of production facilities in the industry, including data indicating plant closings or the underutilization of production capacity;

(ii) The inability of a significant number of firms to carry out domestic production operations at a reasonable level of profit; and

(iii) Significant unemployment or underemployment within the industry; and/or

(2) With respect to the threat of serious injury, data relating to:

(i) A decline in sales or market share, a higher and growing inventory (whether maintained by domestic producers, importers, wholesalers, or retailers), and a downward trend in production, profits, wages, productivity, or employment (or increasing underemployment);

(ii) The extent to which firms in the industry are unable to generate adequate capital to finance the modernization of their domestic plants and equipment, or are unable to maintain existing levels of expenditures for research and development;

(iii) The extent to which the U.S. market is the focal point for the diversion of exports of the article concerned by reason of restraints on exports of such article to, or on imports of such article into, third country markets; and

(3) Changes in the level of prices, production, and productivity.

(f) *Cause of injury.* An enumeration and description of the causes believed to be resulting in the injury, or threat thereof, described under paragraph (e) of this section, and a statement regarding the extent to which increased imports of the subject article are believed to be such a cause, supported by pertinent data;

(g) *Relief sought and purpose thereof.* A statement describing the import relief sought, including the type, amount, and duration, and the specific purposes thereof, which may include facilitating the orderly transfer of resources to more productive pursuits, enhancing competitiveness, or other means of adjustment to new conditions of competition;

(h) *Efforts to compete.* A statement on the efforts being taken, or planned to be taken, or both, by firms and workers in the industry to make a positive adjustment to import competition.

(i) *Critical circumstances.* If the petition alleges the existence of critical circumstances, a statement setting forth the basis for the belief that there is clear evidence that increased imports (either actual or relative to domestic production) of the article are a substantial cause of serious injury, or the threat thereof, to the domestic industry, and that delay in taking action would cause damage to that industry that would be difficult to repair, and a statement concerning the provisional relief requested and the basis therefor.

■ 9. Revise § 206.35 to read as follows:

§ 206.35 Time for determinations, reporting.

(a) *In general.* The Commission will make its determination with respect to injury within 120 days (180 days if critical circumstances are alleged) after the date on which the investigation is initiated. The Commission will make its report to the President no later than 30 days after the date on which its determination is made.

(b) *Perishable agricultural product.* In the case of a request in a petition for provisional relief with respect to a perishable agricultural product that has been the subject of monitoring by the Commission, the Commission will report its determination and any finding to the President not later than 21 days after the date on which the request for provisional relief is received.

(c) *Critical circumstances.* If petitioner alleges the existence of critical circumstances in the petition, the Commission will report its determination regarding such allegation and any finding on or before the 60th day after such filing date.

■ 10. Add § 206.37 to read as follows:

§ 206.37 Limited disclosure of certain confidential business information under administrative protective order.

Except in the case of an investigation under the United States-Jordan Free Trade Area Implementation Act or the NAFTA, the Secretary shall make available to authorized applicants, in accordance with the provisions of § 206.17, confidential business information obtained in an investigation under this subpart.

By order of the Commission.

Issued: January 19, 2012.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012-1500 Filed 1-25-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Deracoxib

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 Novartis Animal Health U.S., Inc. The supplemental NADA provides for veterinary prescription use of deracoxib tablets in dogs for the control of postoperative pain and inflammation associated with dental surgery and the addition of a 12-milligram (mg) size tablet.

DATES: This rule is effective January 26, 2012.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novartis Animal Health U.S., Inc., 3200 Northline Ave., Suite 300, Greensboro, NC 27408, filed a supplement to NADA 141-203 that provides for veterinary prescription use of DERAMAXX (deracoxib) Chewable Tablets in dogs for the control of postoperative pain and inflammation associated with dental surgery and the addition of a 12-mg size tablet. The supplemental NADA is