from the United States, including those that accompanied an individual outside the United States for personal use, if they are reimported into the United States by the same person who exported them, without having been advanced in value or improved in condition by any process or other means while outside the United States; and

(2) Jadeite or rubies mined or extracted from a country other than Burma, and articles of jewelry containing jadeite or rubies mined or extracted from a country other than Burma that are imported by or on behalf of an individual for personal use and accompanying an individual upon entry into the United States.

PART 163—RECORDKEEPING

■ 3. The general authority citation for Part 163, CBP regulations, continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1484, 1508, 1509, 1510, 1624.

■ 4. The Appendix to Part 163 is amended by adding a new listing under section IV in numerical order to read as follows:

Appendix to Part 163—Interim (a)(1)(A) List.

* * * * *

IV. * * *

§ 12.151 Documentation supporting importer's certification on jadeite, rubies, or articles of jewelry containing jadeite or rubies, including an exporter's certification.

* * * * *

Jayson P. Ahern,

Acting Commissioner, U.S. Customs and Border Protection.

Approved: January 12, 2009

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. E9–786 Filed 1–15–09; 8:45 am]

BILLING CODE 9111–14–P

INTERNATIONAL TRADE COMMISSION

19 CFR Part 207

Revised Procedures and Requests for Information During Adequacy Phase of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Final rulemaking.

SUMMARY: The United States International Trade Commission (''the Commission'') amends its Rules of Practice and Procedure to require that responses to notices of institution of five-year reviews be filed within 30 days of publication of the notice, as opposed to the 50-day response period specified in its current rules. It also provides notice of its decision, which does not require a change in its rules, to seek additional information from interested parties at the institution of five-year reviews, and to seek information from purchasers during the adequacy phase of five-year reviews in certain circumstances.

DATES: *Effective Date:* This regulation is effective February 17, 2009.

Applicability Date: This regulation and the other changes to Commission procedures described in this notice will be applicable to five-year reviews instituted on or after March 1, 2009.

FOR FURTHER INFORMATION CONTACT: Marc A. Bernstein, Office of General Counsel, U.S. International Trade Commission, telephone 202–205–3087, or John Ascienzo, Office of Investigations, U.S. International Trade Commission, telephone 202–205–3175. Hearing-impaired individuals can obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by visiting its Web site at *http://www.usitc.gov*.

SUPPLEMENTARY INFORMATION: On July 17, 2008, the Commission published a notice of proposed rulemaking (NOPR) in the **Federal Register**. 73 FR 40992 (July 17, 2008). In that notice the Commission proposed two sets of changes to the procedures it uses during the adequacy phase of five-year reviews that it conducts pursuant to 19 U.S.C. 1675(c). First, the Commission proposed modifying the information it requests interested parties furnish in their responses to the notice of institution it publishes pursuant to section 207.60(d) of the Commission's Rules of Practice and Procedure, 19 CFR 207.60(d), and proposed issuing short questionnaires to purchasers in some circumstances. This set of proposals did not require any amendment to the Commission's regulations. The second proposal sought to amend section 207.61(a) of the Commission's Rules of Practice and Procedure to require that responses to the notice of institution be filed within 30 days after its publication.

Although the Commission considers these rules to be procedural rules that are excepted from the notice and comment requirements of 5 U.S.C. 553(b)(3)(A), the Commission invited the public to comment on the proposed rule amendment and the other proposed changes to its procedures within 60 days of publication of the NOPR in the **Federal Register**. The Commission received substantive comments from the following: (1) The law firm of Wiley Rein on behalf of the Steel Manufacturers Ass'n (SMA); (2) the law firm of Skadden, Arps, Slate, Meagher & Flom (Skadden); (3) the law firm of Kelley Drye & Warren (Kelley); and (4) the law firm of Stewart and Stewart (Stewart).

In adopting these changes to its rules and procedures, the Commission has fully considered the concerns expressed in the comments with respect to the potential burden on parties to reviews and the usefulness of the additional information sought by the Commission. These comments, and the Commission's responses thereto, are discussed comprehensively below. In light of the comments, the Commission intends to review its new information requests and changes to its procedures once it has had sufficient experience with them. In particular, the Commission intends to examine the changes' utility and relevance in attaining the desired objectives, as well as the rate of response by purchasers to the adequacy phase questionnaires.

As required by the Regulatory Flexibility Act, the Commission certifies that the amendment to its regulation will not have a significant impact on small business entities.

Changes in Commission Data Collection

The Commission has decided to adopt the changes in data collection proposed in the NOPR. Accordingly, each notice of institution the Commission issues will contain the additional information requests indicated in Appendix A to the NOPR, and in those reviews in which the Commission does not receive responses to the notice of institution from both domestic interested parties and respondent interested parties, the Commission will transmit brief questionnaires to purchasers, in the format indicated in Appendix B to the NOPR, shortly after it receives responses to the notice of institution. These changes will become effective for reviews instituted on or after March 1, 2009.

The commenters opposed both of the Commission's data collection proposals. With respect to the proposal to seek additional information in the notice of institution, commenters questioned the appropriateness of the Commission's stated objective of obtaining a more complete record to better enable it to decide whether to expedite a review. Skadden contended that the Commission should expedite reviews whenever responses from an interested party group are inadequate and that

Congress never intended the Commission to take considerations such as conditions of competition into account in deciding whether to expedite a review. Kelley expressed a similar view, maintaining that when parties have deliberately chosen not to participate in a review, it is a waste of resources for the Commission and other parties to undertake the costs of a full review. SMA asserted that the sole purpose of information requests in the adequacy phase is to ascertain sufficient commitment to participation in a five-year review.The Commission disagrees with the premise underlying these comments that an inadequate interested party group response should always result in an expedited determination. Neither the statute nor Commission practice dictates such a result. The statute states that ''[i]f interested parties provide inadequate responses to the notice of institution * * * the Commission * * * *may* issue, without further investigation, a final determination based on the facts available.'' 19 U.S.C. 1675(c)(3)(B) (emphasis added). The statutory language indicates that the Commission has the discretion whether to conduct an expedited review when it receives an inadequate response from an interested party group. While the Statement of Administrative Action (SAA) for the Uruguay Round Agreements Act states that the purpose of the expedited review procedure is ''to eliminate needless reviews,'' it does not suggest that all reviews in which an interested party group response may be inadequate are necessarily ''needless.'' H.R. Rep. 103–316, vol. I at 880 (1994). Indeed, in its 1998 rulemaking notice, the Commission expressly indicated that it ''has the discretion to conduct a full review even when interested party responses are inadequate.'' 63 FR 30599, 30604 (June 5, 1998). The circumstances the Commission identified as justifying such an exercise of discretion included mixed responses in grouped reviews (*i.e.*, adequate respondent interested party group responses for some subject countries but not others) and the existence of significant domestic like product issues. *Id.* at 30604. In recent years, the Commission has taken the position that changes in conditions of competition may also warrant conducting a full review even when a respondent interested party group response is inadequate. *E.g., Certain Welded Stainless Steel Pipe from Korea and Taiwan*, Inv. Nos. 731–TA–540–541 (Second Review), USITC Pub. 3877 at 3 (Aug. 2006).

Commenters questioned whether the additional data requests would accomplish the Commission's objective of improving the information available to it in expedited reviews. Three commenters contended that the additional information the Commission seeks will be too limited in temporal scope, because it will concern only one calendar year, to be particularly probative. They asserted that a single year's worth of data may be misleading.

The Commission acknowledges the limitations of a data set that contains data for only one year. Nevertheless, the other data the Commission currently seeks in the notice of institution similarly encompass only a single calendar year. The Commission believes that obtaining additional data concerning capacity, financial information concerning production of the domestic like product, and prices for the domestic like product and subject merchandise in the U.S. and other world markets will improve the quality of the record in the reviews it chooses to expedite. Indeed, none of the commenters directly challenged this proposition. Although commenters expressed concern about the burden of providing the additional information the Commission proposes to collect, the Commission believes that burden will be reasonable and will certainly be less onerous than that involved in supplying data for several years.

Commenters further questioned whether any information purchasers may provide in the proposed ''mini-questionnaires'' will be useful to the Commission. Skadden and SMA contended that because purchasers cannot provide information pertinent to whether interested parties are willing to participate in a review and provide requested information to the Commission, the information they would supply would not be pertinent. Kelley and SMA expressed the concern that purchasers' responses will be skewed by a desire to reduce the price of their inputs. Skadden and Stewart questioned whether the limited number of purchasers likely to receive the mini-questionnaires will be sufficiently representative to provide reliable information. Stewart also observed that the mini-questionnaires may prove burdensome to purchasers, who will be required to furnish the same information a second time should the Commission conduct a full investigation.

The commenters' central objection to this proposal is premised on the view that the only purpose of the adequacy phase of a five-year review is to ascertain whether there are sufficient responses to warrant conducting a full review, and if a group response is inadequate, the Commission must expedite the review. The Commission has previously disagreed with this premise and has reaffirmed the relevance of examining whether there have been significant changes in conditions of competition for the purpose of determining whether a full review is warranted, notwithstanding an inadequate group interested party response. The Commission acknowledges that the information the purchasers will provide in response to their mini-questionnaires will be limited in scope and may reflect the perspective of the submitter. Nevertheless, the Commission currently believes this limited information will provide a useful supplement to the information provided in the responses to the notices of institution as to how the current conditions of competition for the domestic like product and the subject merchandise may differ from those that the Commission examined in prior determinations. The Commission further notes that the responses to the notice of institution also reflect the perspective of the submitter. In addition, no purchaser interests submitted any comments objecting to the proposal. Nevertheless, as previously discussed, the Commission will further consider both the response rate to the mini-questionnaires and the utility of the information they provide once it has obtained experience issuing such questionnaires and analyzing responses to them.

Change in Commission Rule 207.61(a)

In the NOPR, the Commission proposed amending Commission Rule 207.61(a) to require that responses to the notice of institution be submitted within 30 days after publication of the notice, as opposed to the current 50 days. The Commission stated that this change would permit the Commission staff the additional time it would need to engage in the additional information collection and analysis that was contemplated under the proposed new data collection requests. Because the Commission has implemented the proposed new data collection requests, it has also determined to issue the proposed change to Commission Rule 207.61(a) in final form. The amended regulation will apply to all reviews instituted on or after March 1, 2009.

Each of the commenters opposed the proposed change to Commission Rule 207.61(a) on the grounds that a 30-day response period was insufficient. Skadden and Stewart contended that parties need the full 50 days currently

provided in the rule to file their substantive responses to the Commission because they will be devoting the first 30 days of that period preparing responses to the Department of Commerce. SMA stated that current requirements for adequacy comments are arduous and that increasing the amount of information that must be provided while reducing the amount of time available to prepare a submission is problematic. Kelley asserted that domestic producers will put more detailed information in a notice of review if they are aware that no respondent interested parties will participate. Notices of appearance need not be filed until 21 days after the notice of institution, and Kelley asserted that nine days would be insufficient time for a domestic producer to compile this more detailed information.

The commenters' objections proceed largely from the premise that a domestic producer will not begin to prepare its responses to either the Commerce notice of initiation or the Commission notice of institution until these notices are published in the **Federal Register**. The Commission does not agree with this premise. Interested parties are in a position to begin compiling information needed for a five-year review well before the publication of notices in the **Federal Register** beginning the reviews. The parties typically know the date that Commerce and the Commission will publish their **Federal Register** notices many months in advance. The Commission requests standardized information in interested parties' responses to notices of institution; the information requests are generally known prior to publication of the **Federal Register** notice. Similarly, the information that Commerce requires to be submitted in a notice of intent to participate in a sunset review is specified by regulation, and thus will be known well before initiation of the review. Kelley's assertion that responses to the notice of institution contain more detailed information in uncontested reviews than in contested reviews is not consistent with the Commission's experience.

List of Subjects in 9 CFR Part 207

Administrative practice and procedure, investigations.

■ For the reasons stated in the preamble, the Commission amends 19 CFR part 207 as follows:

PART 207—INVESTIGATIONS OF WHETHER INJURY TO DOMESTIC INDUSTRIES RESULTS FROM IMPORTS SOLD AT LESS THAN FAIR VALUE OR FROM SUBSIDIZED EXPORTS TO THE UNITED STATES

■ 1. The authority citation for part 207 continues to read as follows:

Authority: 19 U.S.C. 1336, 1671–1677n, 2482, 3513.

■ 2. Amend § 207.61 by revising paragraph (a) as follows:

§ 207.61 Responses to notice of institution.

(a) *When Information Must Be Filed.* Responses to the notice of institution shall be submitted to the Commission no later than 30 days after its publication in the **Federal Register**.

* * * * *

Issued: January 12, 2009.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E9–860 Filed 1–15–09; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. FDA–2003–N–0209] (Formerly Docket No. 2003N–0341)

RIN 0910–AC23

Requirements for Submission of Bioequivalence Data; Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on the submission of bioequivalence data to require an abbreviated new drug application (ANDA) applicant to submit data from all bioequivalence (BE) studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets bioequivalence criteria in order for FDA to approve the ANDA, but have not typically submitted additional BE studies conducted on the same drug product formulation, such as studies that do not show that the product meets these criteria. FDA is amending the regulation because we now believe that data from additional BE studies may be important in our determination of whether the proposed formulation is bioequivalent to the reference listed drug (RLD), and are relevant to our evaluation of ANDAs in general. In addition, such data will increase our understanding of how changes in components, composition, and methods of manufacture may affect product formulation performance.

DATES: The rule is effective July 15, 2009.

FOR FURTHER INFORMATION CONTACT: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8782.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 29, 2003 (68 FR 61640), FDA proposed to amend its regulations in parts 314 and 320 (21 CFR parts 314 and 320) to require an ANDA applicant to submit data from all BE studies that the applicant conducts on a drug product formulation submitted for approval. Section 505(j)(2)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(2)(A)(iv)) requires that ANDA applicants submit, among other things, information showing that the applicant's drug is bioequivalent to a drug that has previously been approved by FDA. Under the regulations at § 314.3(b), the approved drug product identified by FDA as the drug product on which an ANDA applicant relies for approval is the RLD. The requirement that an ANDA applicant submit information that shows the proposed product is bioequivalent to the RLD is described in FDA's regulations at § 314.94(a)(7). Section 320.24 sets forth the types of evidence acceptable to establish BE. The most common BE studies are those performed on solid oral dosage forms of drugs that are absorbed into the systemic circulation. BE data provide an estimate of the rate and extent of drug absorption for a test and reference product. These data are examined, using statistical procedures, to determine whether the test product meets BE limits.

A BE study may fail to show that a test product meets BE limits because the test product has significantly higher or lower relative bioavailability (i.e., measures of rate and extent of absorption compared to the reference product). In some cases, BE will not be demonstrated because there are inadequate numbers of subjects in the study relative to the magnitude of intrasubject variability, and not because