Parts Installation

(h) As of the effective date of this AD, no person may install on any airplane a water accumulator assembly, P/N 50029–001, 9435015, 50030–001, or 9435014 for Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, or P/N 50033–001 for Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes on the pitot and static lines of the ADC.

Credit for Actions Accomplished in Accordance With Previous Service Information

(i) Replacing water accumulator assemblies in accordance with Bombardier Service Bulletin 670BA–34–147, dated April 1, 2009; or Revision A, dated November 3, 2009 ((for Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes)), before the effective date of this AD is acceptable for compliance with the corresponding replacement required by paragraph (g)(1) of this AD.

(j) Replacing water accumulator assemblies in accordance with Bombardier Service Bulletin 670BA–34–030, dated April 1, 2009; or Revision A, dated November 3, 2009 ((for Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), CL–600–2D15 (Regional Jet Series 705), and CL–600–2D24 (Regional Jet Series 900) airplanes)); before the effective date of this AD, is acceptable for compliance with the corresponding replacement required by paragraph (g)(2) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(k) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; *telephone:* (516) 228–7300; *fax:* (516) 794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(l) Refer to MCAI Transport Canada Civil Aviation Airworthiness Directive CF–2010–37, dated October 28, 2010; Bombardier Service Bulletin 601R–34–147, Revision B, dated March 8, 2011; and Bombardier Service Bulletin 670BA–34–030, Revision B, dated March 23, 2010; for related information.

Material Incorporated by Reference

(m) You must use Bombardier Service Bulletin 601R–34–147, Revision B, dated March 8, 2011; and Bombardier Service Bulletin 670BA–34–030, Revision B, dated March 23, 2010; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; *phone:* 514–855–5000; *fax:* 514–855–7401; *e-mail: thd.crj@aero.bombardier.com; Internet: http://www.bombardier.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on September 28, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–26081 Filed 10–18–11; 8:45 am]

BILLING CODE 4910–13–P

INTERNATIONAL TRADE COMMISSION

19 CFR Part 210

[Docket No. MISC–032]

Rules of Adjudication and Enforcement

AGENCY: International Trade Commission

ACTION: Final rule.

SUMMARY: The United States International Trade Commission (''Commission'') amends its Rules of Practice and Procedure concerning rules of adjudication and enforcement. The amendments are necessary to gather more information on public interest issues arising from complaints filed with the Commission requesting institution of an investigation under Section 337 of the Tariff Act of 1930. The intended effect of the amendments is to aid the Commission in identifying investigations that require further development of public interest issues in the record, and to identify and develop information regarding the public interest at each stage of the investigation.

DATES: Effective November 18, 2011.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, United States International Trade Commission, telephone 202–708–2301. 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 Internet server at *http://www.usitc.gov.*

SUPPLEMENTARY INFORMATION:

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. This rulemaking seeks to update certain provisions of the Commission's existing Rules of Practice and Procedure. The Commission is amending its rules covering investigations under Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) (''Section 337'') in order to increase the efficiency of its Section 337 investigations. Specifically, the changes to the Commission's Rules are for the purpose of improving the Commission's procedures and ensuring the completeness of the record with respect to the required analysis concerning the public interest under Sections 337(d)(1) and (f)(1). There is no change in the Commission's substantive practice with respect to its consideration of the public interest factors in its determinations relating to the appropriate remedy.

The Commission published a notice of proposed rulemaking (''NOPR'') in the **Federal Register** at 75 FR 60671 (Oct. 1, 2010), proposing to amend the Commission's Rules of Practice and Procedure to gather more information on public interest issues. Consistent with its ordinary practice, the Commission invited the public to comment on all the proposed rules amendments. This practice entails the following steps: (1) Publication of an NOPR; (2) solicitation of public comments on the proposed

amendments; (3) Commission review of public comments on the proposed amendments; and (4) publication of final amendments at least thirty days prior to their effective date.

The NOPR requested public comment on the proposed rules within 60 days of publication of the NOPR. In response to requests from the American Intellectual Property Law Association (''AIPLA'') and the Intellectual Property Owners Association (''IPO''), the Chairman granted an extension by letter of December 2, 2010, to allow those entities to submit comments until January 7, 2011. The Commission received a total of eight sets of comments from corporations or organizations, including one each from the ITC Trial Lawyers Association (''ITCTLA''); Microsoft Corp. (''Microsoft''); Intellectual Ventures, LLC (''Intellectual Ventures''); the Ministry of Commerce of the People's Republic of China (''MOFCOM''); the China Chamber of Commerce for Light Industrial Products & Arts-Crafts (''CCCLA''); the Computer & Communications Industry Association (''CCIA''), and the IPO. In addition, the law firm of Adduci, Mastriani & Schaumberg LLP (''AMS'') filed a set of comments. Three sets of comments were received from persons writing in their individual capacities, *viz.,* Ms. Mary White, Mr. Steven Beard, and a group of economists including Messrs. Fei Deng, Greg Leonard, and Mario Lopez. The IPO's comments were filed one week late on January 14, 2011. The AIPLA did not submit comments.

The Commission has carefully considered all comments that it received. The Commission's response is provided below in a section-by-section analysis. The Commission appreciates the time and effort of the commentators in preparing their submissions.

As required by the Regulatory Flexibility Act, the Commission certifies that these regulatory amendments will not have a significant impact on small business entities.

Overview of the Amendments to the Regulations

The final regulations contain eleven (11) changes from those proposed in the NOPR. These changes are summarized here.

First, with regard to rule 210.12, relating to the complaint, the Commission has determined that it will not require complainants to include public interest allegations in the complaint. Second, the Commission has determined to add final rule 210.8(b) to require complainants to file a separate statement of public interest concurrently with the complaint. Final rule 210.8(b) contains a list of the issues that a complainant should address in its public interest statement, which is similar to the list contained in proposed rule 210.12(a)(12). Third, the Commission has determined to add final rule 210.8(c)(1) to provide for the responses to a Commission pre-institution **Federal Register** notice that will solicit comments regarding the public interest, including addressing complainant's filing under rule 210.8(b), from proposed respondents and the public upon receipt of a complaint. Included in this section is a requirement that public interest submissions are due eight (8) calendar days after publication of the pre-institution notice in the **Federal Register**. Fourth, the Commission has added final rule 210.8(c)(2) to provide that complainants may file reply submissions to responses submitted by the public and proposed respondents in response to the Commission's pre-institution **Federal Register** notice under final rule 210.8(c)(1). Any such replies are due within three (3) calendar days following the filing of submissions by proposed respondents and the public. Fifth, current rule 210.8(b) is redesignated 210.8(d).

Sixth, with regard to proposed rule 210.13(b), the Commission has determined that respondents will likewise not be required to address the public interest in their response to the complaint. Therefore, proposed rule 210.13(b) will not appear in the final rules. Seventh, the Commission has determined to add final rule 210.14(f) to require respondents to submit a statement of public interest in response to complainants' filings under § 210.8(b) and (c)(2) when the Commission has delegated the matter of public interest to the presiding administrative law judge (''ALJ'').

Eighth, the Commission has determined to amend proposed rule 210.50(a)(4) to clarify that the parties are requested, but not required, to file comments on the public interest thirty (30) days after issuance of the presiding ALJ's recommended determination (''RD'') on remedy, bonding, and where ordered, the public interest. These comments may include any information relating to the public interest, including any updates to the information provided pursuant to sections 210.8(b) and (c) and 210.14(f), and are limited to five (5) pages, inclusive of attachments. Members of the public will be given an opportunity to comment on the RD in response to a **Federal Register** notice that will be issued by the Commission after issuance of the presiding ALJ's RD.

Ninth, the Commission has determined to redesignate the currently undesignated paragraph following current rule 210.50(a)(4) as final rules 210.50(a)(4)(i), (ii), (iii), and (iv).

Tenth, the Commission has determined to amend rule 210.10(b) to indicate that the comments received during the pre-institution period—under final rules 210.8(b) and (c)—are the general basis for the Commission's determination as to whether to delegate the issue of public interest to the ALJ. Rule 210.10(b) is also amended to clarify the limits on discovery when the Commission orders the ALJ to consider the public interest. Eleventh, the Commission has determined to add final rule 210.42(a)(1)(ii)(C) to clarify that, when ordered to take evidence on the public interest, the ALJ shall include analysis of the public interest in his RD.

A comprehensive explanation of the rule changes is provided in the section-by-section analysis below. The section-by-section analysis includes a discussion of all modifications suggested by the commentators. As a result of some of the comments, the Commission has determined to modify several of the proposed amendments and to add several new sections to the final rule as summarized above. The section-by-section analysis will refer to the rules as they appeared in the NOPR. Any new rules will be discussed with respect to the previously proposed rules.

Section-by-Section Analysis

19 CFR Part 210

Subpart C—Pleadings

Section 210.12

The NOPR proposed to amend § 210.12 by adding a subsection (12) to § 210.12(a) to require that the complainant provide in its complaint specific information regarding how issuance of an exclusion order and/or a cease and desist order in an investigation could affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

The NOPR further proposed adding a paragraph (k) to § 210.12 to provide that, when a complaint is filed, the Secretary to the Commission will publish a notice in the **Federal Register** soliciting comments from the public and the proposed respondents on any public interest issues arising from the complaint. Under the proposed rules, these comments would be limited to

five pages and would be required to be filed within five days of publication of the notice. The purpose of the proposed amendments to 210.12 was to gather information for the Commission to consider in deciding whether to refer the public interest issues to the ALJ.

Microsoft, Intellectual Ventures, and AMS contend that if the Commission seeks more information on the public interest, it would be sufficient to allow the parties and the public to comment in response to a pre-institution **Federal Register** notice published immediately after the filing of the complaint. Microsoft, Intellectual Ventures, and AMS are of the view that it would be unnecessary and burdensome to require the complaint and the respondents' responses to the complaint to include information on the public interest in addition to any submissions the parties might file in response to the pre-institution **Federal Register** notice.

AMS states that the Commission's recent practice of soliciting comments at the beginning of the investigation is a good one and should be made a permanent part of Section 337 procedure. AMS notes that many parties and members of the public have taken advantage of the opportunity to file such comments since the Commission began soliciting them in 2010. AMS states that ''[i]t would not be consistent with the remedial purpose of Section 337 if potential complainants were deterred from coming to the ITC due to concerns about the burdens associated with addressing public interest issues before there has been any adjudication of violation or the scope of the remedy.''

Microsoft states that requiring information on the public interest in the complaint and responses thereto would be unduly burdensome in light of the rare instances where the public interest has been a factor in deciding whether to issue relief. Microsoft states that to the extent the Commission believes amendment to its rules is necessary, the pre-institution **Federal Register** notice alone would identify to the Commission the few instances warranting early development of public interest information. Microsoft, however, urges the Commission to make clear that the Commission is not expanding the breadth of the statutory public interest factors with any amendment. It believes that open-ended and undefined submissions regarding ''competitive conditions in the United States economy'' would provide little guidance to the Commission.

According to Intellectual Ventures, the public interest information required in the complaint under the proposed rules may not be in the possession of many complainants and determining the potential public interest impact of a hypothetical remedy is a highly speculative endeavor, particularly at the outset of an investigation. Moreover, the proposed rules could place a burden upon potential complainants to conduct extensive research on subjects far outside their businesses and expertise. Intellectual Ventures believes a pleading requirement would not only burden the parties, but would run the risk of reintroducing at least the perception that the Commission is making a determination of injury as part of the determination of violation, which is in direct opposition to the Congressional mandate that there is no longer an injury requirement in Section 337 investigations. Intellectual Ventures is particularly concerned about domestic industries that are based on the exploitation of intellectual property through engineering, research and development, and licensing. Intellectual Ventures also states that ''by placing a de facto burden on complainant to deny the existence of public interest concerns—a burden which the statute does not require them to meet—this proposal may deter some complainants from coming to the ITC at all, which would be contrary to the purpose and intent of Section 337 to protect domestic industries from unfair import competition.'' While Intellectual Ventures is opposed to any change in the current rules, it states that it is better to solicit comments through the **Federal Register** during the pre-institution stage of the investigation than to require the information in the pleadings.

Although not part of the official comments, on January 19, 2011, during the Third Annual Live at the ITC—Forum on Section 337 of the Tariff Act of 1930, panelists expressed concerns that ordering a complainant to act against its own interest by listing public interest issues in the complaint is essentially unfair because the statute directs the issuance of an exclusion order unless, upon consideration of the public interest, the Commission decides not to do so. Another concern was the burden such a requirement would place on non-practicing entities (NPEs) which might not actually know what their licensees are doing with the asserted patented technology. One panelist raised the possibility that NPEs might be subject to sanctions if they could not truthfully answer the public interest questions in the complaint.

On the other hand, the ITCTLA does not object to requiring public interest information in the complaint.

Commission Response

The Commission has determined that it will not require complainants to include public interest allegations in the complaint. Instead, the Commission will obtain public interest information from the parties early in the investigation in a format different from that which was proposed in the NOPR. Specifically, instead of including public interest information in the complaint, complainants will be required to file a separate statement of public interest concurrently with the filing of the complaint. If a complainant includes information which it deems confidential in the submission, it will be required to also file a nonconfidential version concurrently with its complaint. This final rule will be designated as 210.8(b). Current rule 210.8(b) will be redesignated as 210.8(d), as discussed below.

The ITCTLA suggests that the Commission solicit even more specific information concerning the public interest. In particular, the ITCTLA suggests that the complainant identify, to the best of its knowledge, the ''like or directly competitive articles,'' and how the complainant's requested relief would affect consumers in the United States. The ITCTLA also suggests different language for some of the Commission's final rules. For instance, it suggests that the amendments be more consistent with the statutory public interest factors and proposes that a fifth provision be included that would require a statement as to how a company's requested relief would affect consumers in the United States. The ITCTLA also suggests that the comments be directed to the ''requested'' exclusion order and cease and desist order rather than to a generic exclusion order and cease and desist order.

MOFCOM suggests that the public interest considerations be expanded to include the sales of upstream and downstream products of the subject articles, and the operation condition of the importer, exporter, and retailer of the subject articles. The CCCLA suggests that the public interest factors include market conditions and the competitiveness of importers, distributors and retailers in the upstream and downstream industry related to the subject articles.

Economists Deng, Leonard, and Lopez suggest that the Commission refrain from seeking information on an exhaustive list and instead lay out general types of information that might prove fruitful. Some examples of information they deem relevant in evaluating the impact of an exclusion

order, are as follows: (1) The costs and time it would take a consumer to switch to substitute products, (2) the loss in consumer welfare due to reduction in product variety in differentiated product industries, (3) the potential for a price increase from the reduction in competition, (4) the ability of non-infringing firms to offer close substitutes and the time required to do so, (5) potential entrants, i.e., potential new suppliers of substitute goods, and (6) the potential profit lost by vertically-related firms versus the potential profit gained by competitors and competitors' vertically-related firms.

The CCIA suggests that the Commission adopt for its public interest rules the standard for obtaining a permanent injunction in a federal district court laid out by the Supreme Court in *eBay Inc* v. *MercExchange, L.L.C.,* 547 U.S. 388 (2006) (''*eBay*''). The CCIA suggested that the Commission would need to do so in order to comply with United States obligations under Article III: 4 of the GATT, specifically, a GATT decision, *United States—Section 337 of the Tariff Act of 1930* (Nov. 7, 1989).

Commission Response

The Commission has determined that complainants' statement concerning the public interest under final rule 210.8(b) should be focused as follows: (a) Explain how the articles potentially subject to the order are used in the United States; (b) identify any public health, safety, or welfare concerns relating to the requested remedial orders; (c) identify like or directly competitive articles that complainant, its licensees, or third parties make which could replace the subject articles if they were to be excluded; (d) indicate whether the complainant, its licensees, and/or third parties have the capacity to replace the volume of articles subject to the potential orders in a commercially reasonable time in the United States; and (e) state how the requested relief would impact consumers. These topics will replace those currently listed in proposed rule 210.12(a)(12). The Commission has determined that the final rules will not adopt the test for permanent injunctions articulated in *eBay*.

Several parties (Mary White, the ITCTLA, AMS, MOFCOM, and the CCCLA) state that five days is too short a time for proposed respondents and the public to respond to the pre-institution **Federal Register** notice soliciting comments. The ITCTLA suggests extending this time period to seven business days; MOFCOM suggests 10 calendar days; and AMS and the CCCLA suggest 15 calendar days. ITCTLA suggests that an additional period of seven (7) business days be allowed for responses to these early comments.

Commission Response

The Commission has determined to provide more time for public comment beyond what was proposed in the NOPR (rule 210.12(k)). Specifically, the Commission will require that public interest submissions be due eight (8) calendar days after publication of the pre-institution notice in the **Federal Register**. If any such submission includes information which the submitting entity deems confidential, it will be required to also file a nonconfidential version concurrently with its confidential submission. This requirement will appear in final rule 210.8(c)(1).

Steven Beard suggests that public comments in response to the pre-institution **Federal Register** notice should be forwarded to the parties in the adjudicative proceeding.

Commission Response

The Commission has determined that public interest comments should not be forwarded by the Commission to the complainant and proposed respondents, since the Commission's Electronic Document Information System (EDIS) is available to allow access to any comments that are filed. No amendments to the final rules will be made in this regard.

MOFCOM criticizes the ''and/or'' language of the proposed amendment to § 210.12(k), which it believes suggests that in some cases either, but not both, the public or the proposed respondents will have the right to comment on the public interest.

Commission Response

This is not the intent of the amendments, so to address this comment, final rule 210.8(c)(1) states that both proposed respondents and the public may respond to complainants' filings under 210.8(b).

The ITCTLA points out that under the proposed amendment to rule 210.13, respondents are permitted to submit a formal response to any public interest submissions made by members of the general public pursuant to proposed rules 210.12(k), but that no such opportunity exists as a matter of right for the complainant to do so. The ITCTLA proposes that Rule 210.12(a)(13) be added to afford a complainant an opportunity to file a reply to any comments received from the general public and respondents.

Commission Response

The Commission has determined that the complainant will be allowed under final rule 210.8(c)(2) to file a reply submission to responses submitted by the public and proposed respondents to the Commission's pre-institution notice. Any such replies are due within three (3) calendar days of the filings under final rule 210.8(c)(1) and are limited to five (5) pages, inclusive of attachments. If a complainant includes information that it deems confidential in the submission, it will be required to also file a nonconfidential version concurrently with its confidential submission.

Section 210.13

The NOPR proposed adding a subsection (4) to section 210.13(b) to require respondents' response to the complaint to address the public interest statements made in the complaint and any comments received from the public with respect to the public interest.

The ITCTLA proposes that the respondent be allowed to amend or supplement the public interest statement contained in its response to the complaint and notice of investigation to respond to any replies that might be filed by complainants. The ITCTLA recommends that since this submission is made early in the investigation, the respondent be permitted to supplement its public interest submission under proposed Rule 210.13(b)(4), where necessary and with good cause shown.

Commission Response

Since the Commission has determined that complainants will not be required to include public interest information in the complaint, respondents will likewise not be required to address the public interest in the response to the complaint. The Commission has, however, determined that respondents must submit a mandatory statement of public interest if the Commission has delegated the matter of public interest to the ALJ, as discussed below in conjunction with proposed amendments to rule 210.50. This provision is reflected in final rule 210.14(f).

Subpart G—Determinations and Actions Taken

Section 210.50

The NOPR further proposed to add language to section 210.50(a)(4) to provide that, after the service of the presiding ALJ's RD on remedy and bonding, the parties are instructed to submit to the Commission within thirty (30) days any information relating to the

public interest, including any updates to the information provided in the complaint and response, as required by the proposed amendments to §§ 210.12 and 210.13. Members of the public would also be permitted to submit information with respect to the public interest under the proposed rule.

The NOPR further proposed to amend section 210.50(b)(1) to provide that unless the Commission orders otherwise, an ALJ shall not take evidence on the issue of the public interest for purposes of the RD under § 210.42(a)(1)(ii). If the Commission orders the ALJ to take evidence on the public interest, the extent of the taking of discovery by the parties shall be at the discretion of the presiding ALJ.

The ITCTLA, IPO, Microsoft, and Intellectual Ventures are concerned that, by requiring public interest submissions subsequent to the issuance of the RD but prior to the issuance of the Commission's notice of review, a misperception may be created that the Commission is weighing public interest information as part of its threshold merits inquiry on review. The ITCTLA further points out that at this stage of the investigation, it is not known what, if any, portions of the final initial determination (''ID'') the Commission has taken under review. Thus, if the Commission determines not to review a final ID finding no violation, or determines to review and remand issues to the ALJ, any submissions on the public interest at this time would be irrelevant or untimely.

Commission Response

The Commission has determined to implement in its final regulations its current practice of requesting party comments on the public interest within thirty (30) days after the RD issues, under final rule 210.50(a)(4). Solicitation of these comments is not limited to cases in which the Commission has delegated the public interest issue to the ALJ. Final rule 210.50(a)(4) has been amended to clarify that the parties are requested, but not required, to file comments under this provision. Such submissions are limited to five (5) pages, inclusive of attachments. The final rule does not allow members of the public to submit similar comments. Rather, the Commission will issue a **Federal Register** notice soliciting comments from the public after an RD issues. Additionally, the Commission has determined to amend rule 210.50(a)(4) to clarify that the undesignated paragraph following current rule 210.50(a)(4) will be preserved as rule § 210.50(a)(4)(i), (ii), (iii), and (iv) in compliance with **Federal Register** requirements.

With respect to the proposed amendments to rule 210.50(b)(1), while generally supporting the Commission's efforts to develop a better record on the public interest, the ITCTLA states that it expects that the Commission will rarely refer the public interest issue to the ALJ and that the proposed rules will not change the Commission's practice substantively. The ITCTLA believes the proposed rules balance the interests of complainants, respondents, and the public by giving each a fair opportunity to present public interest issues early in the investigation and to update information at each stage of the investigation. The ITCTLA warns that delegation of the issue of public interest to the ALJ has the ''potential for a significant expansion of the scope of discovery in Section 337 investigations, particularly with respect to third-party discovery.'' The ITCTLA and Intellectual Ventures state that discovery regarding the public interest may lead to significant party and non-party costs, and the ITCTLA notes that discovery could lead to an extension of the time required to complete investigations. In this connection, the ITCTLA suggests that the Commission limit the scope of the public interest issue that it may delegate to the ALJ in a given case based on the complainant's statement of what articles are like or directly competitive. Specifically, the ITCTLA suggests that the Commission include a preamble stating that it expects ALJs to limit such discovery appropriately, with particular consideration for the interests of third parties, and to ensure that public interest discovery does not delay the investigation and is not used improperly.

Intellectual Ventures, Microsoft, and AMS state that the current rules, which solicit comments on the public interest and analysis of public interest evidence only after a final ID and RD is issued by the presiding ALJ, are adequate. Intellectual Ventures believes that consideration of the public interest as implemented in the NOPR would have a detrimental effect on Section 337 by increasing the burdens on Commission resources, particularly those of the ALJs, and on the parties. Intellectual Ventures submits that Section 337's statutory framework puts the public interest in issue only near the end of an investigation, after a violation is found and an appropriate remedy is determined. It argues that, given the infrequency with which genuine public interest concerns have been implicated in Section 337 investigations, early consideration of the factors is neither necessary nor appropriate in most investigations. It points out that consideration of the public interest at an early stage may encompass investigations where public interest considerations are non-existent, or will not have an impact by the time the Commission reaches a determination on violation, e.g., some issues could be mooted if patents are found not infringed or invalid.

Intellectual Ventures suggests that the final version of rule 210.50 provide for the Commission to delegate only the gathering of evidence to the ALJ, such that the ALJ would collect information and forward it to the Commission without analyzing or addressing the issue himself. Intellectual Ventures expresses concern that allowing the ALJ to both take evidence on the public interest and analyze that evidence would run afoul of Congress's decision, reflected in the 1988 amendments to the Trade Act, to eliminate the injury requirement in Section 337 investigations. Intellectual Ventures also notes that the costs associated with public interest discovery could potentially discourage potential complainants from making use of Section 337 proceedings particularly due to the broad nature of the public interest factors addressed in § 337(d) and (f). Intellectual Ventures expresses concern at the implication that the public will not have any input on the public interest issue during discovery, while also questioning the feasibility of having non-parties present evidence concerning the public interest during discovery. Intellectual Ventures further submits that leaving discovery on the public interest to the ALJs' discretion will lead to inconsistent practices among the ALJs, and ostensibly, inconsistent results in the analysis of public interest evidence.

The IPO supports the Commission's intent of furthering its efforts under the statute to consider the effect of any remedial relief granted in Section 337 investigations. It is concerned, however, that the proposed rule delegates a new obligation to the ALJs, who are already faced with challenging time lines. According to the IPO, delegating the collection of evidence to the ALJs places a significant, and in the vast majority of cases, a needless burden on them at a time when caseloads are growing and target dates have lengthened. It is also concerned that the new rules interject the public interest consideration into the investigation too early, creating a situation where the violation determination would be improperly

influenced by the public interest considerations.

Microsoft is concerned that the proposed amendments will unnecessarily interject ''additional (and potentially burdensome) factual, contention, and expert discovery in the name of 'public policy' '' that does not truly correspond with the purpose of the statute. It notes that the public interest has overridden a Commission order in only a few cases, and states that the application of any new rules should be correspondingly limited to the narrow instances in which public interest concerns are truly relevant. Microsoft asserts that information received at the beginning of the investigation may be out of date or otherwise irrelevant by the time any exclusion order would issue.

AMS states that, historically, the public interest rarely has been relevant in the administration of Section 337. It asserts that referring the public interest issue to the ALJ would, in most cases, be superfluous and premature, noting that a large percentage of cases settle or result in a determination of no violation. The IPO and Intellectual Ventures comment that referring the public interest issue to the ALJ will increase the instances of discovery abuse, particularly in regard to third parties. The ITCTLA also warns that the proposed rules could have the unintended consequence of discovery abuse, particularly in regard to third parties. Intellectual Ventures and Microsoft believe that the proposed rules amendments could overwhelm the Commission process at all stages, particularly by overburdening the ALJ, and lead to longer target dates for the completion of investigations.

Mary White suggests that the Commission clarify that the ALJ would not be allowed to take public interest evidence, or consider the public interest comments, unless ordered to do so by the Commission.

On the other hand, Steven Beard suggests that an ALJ should be able to take evidence on the issue of the public interest, without restrictions, in all investigations and should be mandated to address the substantive issues raised in the public comments when writing their decisions. MOFCOM also believes the ALJ should always be empowered to take evidence on and to address the public interest without reliance on a Commission order.

Commission Response

Rule 210.10(b) has been amended to indicate that the comments received during the pre-institution period—under final rules 210.8(b) and (b)—are the general basis for the Commission's determination as to whether to delegate the issue of public interest to the ALJ. Since proposed rule 210.50(b)(1) clearly states that ''[u]nless the Commission orders otherwise, an ALJ shall not take evidence on the issue of the public interest * * *[,]'' the final rule will not be amended in that respect. The amendment to rule 210.10(b), however, makes clear that, when directed to consider the public interest, the ALJ is expected to limit public interest discovery appropriately, with particular consideration for third parties, and not allow such discovery to delay the investigation or be used improperly. The Commission notes that, when the ALJ is not directed to consider the public interest, the proposed amendments do not expand scope of discovery beyond the issues bearing upon violation. Furthermore, the Commission has amended current rule 210.42(a)(1)(ii) to include § 210.42(a)(1)(ii)(C), which provides that, when ordered to take evidence on the public interest, the ALJ shall include analysis of the public interest in his RD.

Regulatory Analysis of Proposed Amendments to the Commission's Rules

The Commission has determined that the final rules 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.

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. Although the Commission chose to publish a notice of proposed rulemaking, these regulations are ''agency rules of procedure and practice,'' and thus are exempt from the notice requirement imposed by 5 U.S.C. 553(b).

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

No actions are necessary under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) because the final 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 final 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.*). Moreover, they 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 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.*), because it is part of an administrative action or investigation against specific individuals or entities. 44 U.S.C. 3518(c)(1)(B)(ii).

List of Subjects in 19 CFR Part 210

Administration practice and procedure, Business and industry, Customs duties and inspection, Imports, Investigations.

For the reasons stated in the preamble, 19 CFR part 210 is amended as set forth below:

PART 210—ADJUDICATION AND ENFORCEMENT

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 19 U.S.C. 1333, 1335, and 1337.

■ 2. Amend § 210.8 by redesignating paragraph (b) as paragraph (d), and adding new paragraphs (b) and (c) to read as follows:

§ 210.8 Commencement of reinstitution proceedings.

* * * * *

(b) *Provide specific information regarding the public interest.* Complainant must file, concurrently with the complaint, a separate statement of public interest, not to exceed five pages, inclusive of attachments, addressing how issuance of the requested relief, i.e., a general exclusion order, a limited exclusion order, and/or a cease and desist order, in this investigation could affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. In particular, the submission should:

(1) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(2) Identify any public health, safety, or welfare concerns relating to the requested remedial orders;

(3) Identify like or directly competitive articles that complainant, its licensees, or third parties make

which could replace the subject articles if they were to be excluded;

(4) Indicate whether the complainant, its licensees, and/or third parties have the capacity to replace the volume of articles subject to the requested remedial orders in a commercially reasonable time in the United States; and

(5) State how the requested remedial orders would impact consumers.

(c) *Publication of notice of filing.* (1) When a complaint is filed, the Secretary to the Commission will publish a notice in the **Federal Register** inviting comments from the public and proposed respondents on any public interest issues arising from the complaint and potential exclusion and/or cease and desist orders. In response to the notice, members of the public and proposed respondents may provide specific information regarding the public interest in a written submission not to exceed five pages, inclusive of attachments, to the Secretary to the Commission within eight (8) calendar days of publication of notice of the filing of a complaint. Comments that substantively address allegations made in the complaint will not be considered. Members of the public and proposed respondents may address how issuance of the requested exclusion order and/or a cease and desist order in this investigation could affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Submissions should:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns relating to the requested remedial orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make which could replace the subject articles if they were to be excluded;

(iv) Indicate whether the complainant, its licensees, and/or third parties have the capacity to replace the volume of articles subject to the requested remedial orders in a commercially reasonable time in the United States; and

(v) State how the requested remedial orders would impact consumers.

(2) Complainant may file a reply to any submissions received under paragraph (c)(1) of this section not to exceed five pages, inclusive of attachments, to the Secretary to the Commission within three (3) calendar days following the filing of the submissions.

* * * * *

■ 3. Amend § 210.10 by revising paragraph (b) to read as follows:

§ 210.10 Institution of investigation.

* * * * *

(b) An investigation shall be instituted by the publication of a notice in the **Federal Register**. The notice will define the scope of the investigation and may be amended as provided in § 210.14(b) and (b). The Commission may order the administrative law judge to take evidence and to issue a recommended determination on the public interest based generally on the submissions of the parties and the public under § 210.8(b) and (c). If the Commission orders the administrative law judge to take evidence with respect to the public interest, the administrative law judge will limit public interest discovery appropriately, with particular consideration for third parties, and will ensure that such discovery will not delay the investigation or be used improperly. Public interest issues will not be within the scope of discovery unless the administrative law judge is specifically ordered by the Commission to take evidence on these issues.

* * * * *

■ 4. Amend § 210.14 by revising the section heading and adding paragraph (f) to read as follows:

§ 210.14 Amendments to pleadings and notice; supplemental submissions; counterclaims; respondent submissions on the public interest.

* * * * *

(f) *Respondent submissions on the public interest.* When the Commission has ordered the administrative law judge to take evidence with respect to the public interest under § 210.50(b)(1), respondents must submit a statement concerning the public interest, including any response to the issues raised by the complainant pursuant to § 210.8(b) and (c)(2), at the same time that their response to the complaint is due. This submission must be no longer than five pages, inclusive of attachments.

■ 5. In § 210.42, revise the heading of paragraph (a)(1)(ii) and add paragraph (a)(1)(ii)(C) to read as follows:

§ 210.42 Initial determinations.

(a)(1)(i) * * *

(ii) *Recommended determination on issues concerning permanent relief, bonding, and the public interest.* * * *

* * * * *

(C) The public interest under sections 337(d)(1) and (f)(1) in investigations where the Commission has ordered the administrative law judge under § 210.50(b)(1) to take evidence with respect to the public interest.

* * * * *

■ 6. In § 210.50, revise paragraph (a)(4) and (b)(1) to read as follows:

§ 210.50 Commission action, the public interest, and bonding by respondents.

(a) * * *

(4) Receive submissions from the parties, interested persons, and other Government agencies and departments with respect to the subject matter of paragraphs (a)(1), (a)(2), and (a)(3) of this section. After a recommended determination on remedy is issued by the presiding administrative law judge, the parties are requested to submit to the Commission, within 30 days from service of the recommended determination, any information relating to the public interest, including any updates to the information requested by §§ 210.8(b) and (c) and 210.14(f). Any submissions under this section are limited to 5 pages, inclusive of attachments.

(i) When the matter under consideration pursuant to paragraph (a)(1) of this section is whether to grant some form of permanent relief, the submissions described in paragraph (a)(4) of this section shall be filed by the deadlines specified in the Commission notice issued pursuant to § 210.46(a).

(ii) When the matter under consideration is whether to grant some form of temporary relief, such submissions shall be filed by the deadlines specified in § 210.67(b), unless the Commission orders otherwise.

(iii) Any submission from a party shall be served upon the other parties in accordance with § 210.4(g). The parties' submissions, as well as any filed by interested persons or other agencies shall be available for public inspection in the Office of the Secretary.

(iv) The Commission will consider motions for oral argument or, when necessary, a hearing with respect to the subject matter of this section, except that no hearing or oral argument will be permitted in connection with a motion for temporary relief.

(b)(1) With respect to an administrative law judge's authorization to take evidence or other information and to hear arguments from the parties and other interested persons on the issues of appropriate Commission action, the public interest, and bonding by the respondents for purposes of an initial determination on temporary relief, see §§ 210.61, 210.62, and 210.66(a). For purposes of the

recommended determination required by § 210.42(a)(1)(ii), an administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons on the issues of appropriate Commission action and bonding by the respondents upon order of the Commission. Unless the Commission orders otherwise, and except as provided for in paragraph (b)(2) of this section, an administrative law judge shall not take evidence on the issue of the public interest for purposes of the recommended determination under § 210.42(a)(1)(ii).

* * * * *

Issued: October 11, 2011.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–26664 Filed 10–18–11; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. FDA 1993–N–0259 (Formerly Docket No. 1993N–0085)]

Beverages: Bottled Water Quality Standard; Establishing an Allowable Level for di(2-ethylhexyl)phthalate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by establishing an allowable level for the chemical di(2-ethylhexyl)phthalate (DEHP). As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for DEHP at least once each year under the current good manufacturing practice (CGMP) regulations for bottled water. Bottled water manufacturers are also required to monitor their source water for DEHP as often as necessary, but at least once every year unless they meet the criteria for source water monitoring exemptions under the CGMP regulations. This final rule will ensure that FDA's standards for the minimum quality of bottled water, as affected by DEHP, will be no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water.

DATES: This rule is effective April 16, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of April 16, 2012.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1639. Hearing-impaired or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 4, 1993 (58 FR 41612), FDA published a proposal (''the 1993 proposed rule'') to revise the bottled water quality standard regulations in 21 CFR part 103 (now 21 CFR 165.110(b)) to establish or modify the allowable levels in bottled water for 5 inorganic chemicals and 18 synthetic organic chemicals, and to maintain the existing allowable level for the inorganic chemical sulfate. As required under Section 410 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA proposed these revisions in response to the publication by EPA of a final rule (57 FR 31776; July 17, 1992) that established national primary drinking water regulations (NPDWRs) consisting of maximum contaminant levels (MCLs) for the same 23 chemicals and establishing an MCL for sulfate in public drinking water under the Safe Drinking Water Act (SDWA). In a final rule published March 26, 1996 (61 FR 13258), FDA maintained its existing allowable level for sulfate and adopted the proposed allowable levels for the 5 inorganic chemicals and 17 of the synthetic organic chemicals. FDA deferred final action on the proposed allowable level of 0.006 milligrams/liter (mg/L) for the chemical DEHP, in response to a comment stating that the proposed allowable level conflicted with an existing prior sanction for this substance in § 181.27 (21 CFR 181.27).

In the **Federal Register** of April 1, 2010 (75 FR 16363), FDA announced that it was reopening the comment period for the 1993 proposed rule to seek further comment on finalizing the allowable level for DEHP in the bottled water quality standard. At the same time, FDA addressed the issue of the prior sanction for the use of DEHP under § 181.27, which resulted in deferral of final action in 1996. FDA also provided updates on the use of DEHP in bottled water bottles and lid gaskets, and on international standards for DEHP in bottled water. Finally, FDA provided information on analytical methods for measuring DEHP that were adopted by EPA after the 1993 proposed rule and sought comment on the possible inclusion of these methods in a final regulation.

II. Summary of and Response to Comments

The agency received 10 responses, each containing one or more comments, to the April 1, 2010, **Federal Register** document reopening the comment period for the 1993 proposed rule. The agency previously received 13 responses, each containing one or more comments, to the 1993 proposed rule. Some comments addressed issues that are outside the scope of this final rule (*e.g.,* monitoring requirements, other chemicals, and food labeling), and thus will not be discussed here.

Most comments supported adoption of an allowable level for DEHP. As noted previously, one comment received in response to the 1993 proposed rule stated that the proposed allowable level for DEHP conflicted with an existing prior sanction for this substance in § 181.27. This comment also stated that DEHP is routinely used as a plasticizer in gaskets, and that such gaskets are permitted for use under relevant European national regulations. FDA responded to this comment in the April 1, 2010, **Federal Register** document. Briefly, FDA stated that the prior sanction for the use of DEHP in § 181.27 does not preclude the agency from establishing an allowable level for DEHP in the bottled water quality standard under § 165.110(b). FDA also stated that it appears that DEHP currently is not used in caps or closures for bottled water in the United States (Ref. 1), and that DEHP use is not permitted under European Commission regulations for plastic caps or plastic lid gaskets in metal caps (Ref. 2). Finally, FDA stated that several international organizations have adopted standards for DEHP that are the same or similar to the proposed allowable level of 0.006 mg/L, and that the International Bottled Water Association (IBWA), a trade association representing a large segment of the U.S. bottled water industry, adopted EPA's 0.006 mg/L standard for DEHP (40 CFR 141.61(c)) in its Model Code by 1995, suggesting that U.S. manufacturers already are able to meet the proposed level (Refs. 3 and 4). FDA did not receive any comments disagreeing with FDA's conclusions.

Two comments received in response to the April 1, 2010, **Federal Register** document opposed action related to DEHP in bottled water. The first