Note 3: The subject of this AD is addressed in British airworthiness directive 005–05–95.

(g) This amendment becomes effective on November 19, 1997.

Issued in Renton, Washington, on October 7, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–27089 Filed 10–14–97; 8:45 am]

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DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

15 CFR Part 400

[Docket No. 97092934–7234–01]; Order No. 929

RIN 0625–AA49

Technical Amendments to Regulations of the Foreign-Trade Zones Board

AGENCY: Foreign-Trade Zones Board, International Trade Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Foreign-Trade Zones (FTZ) Board adopts the following technical amendments to its regulations to reflect recent changes both to the Foreign-Trade Zones Act of 1934 (''FTZ Act'') and in the organizational structure of the United States Customs Service.

EFFECTIVE DATE: October 15, 1997.

FOR FURTHER INFORMATION CONTACT: John J. Da Ponte, Jr., Executive Secretary, Foreign-Trade Zones Board, room 3716, U.S. Department of Commerce, Pennsylvania Avenue and 14th Street NW, Washington, DC 20230 (202/482–2862).

SUPPLEMENTARY INFORMATION:

Background

The regulations of the Foreign-Trade Zones Board are amended to conform with the following changes: (1) An amendment to the FTZ Act, pursuant to section 910 of the National Defense Authorization Act of 1996, Pub. L. 104–201, 110 Stat. 2422, 2620 (1996), which removed the Secretary of the Army from membership on the Foreign-Trade Zones Board; and 2) recent revisions by the U.S. Customs Service to its organizational structure, which eliminated Regional Commissioner and District Director positions, broadening the role of Port Directors.

Classification

This rulemaking action was determined to be not significant for purposes of Executive Order 12866. The Administrative Procedure Act requirements of notice and comment and delayed effective date are unnecessary for these technical amendments because the FTZ Board has no discretion in making these amendments which are required by Pub. L. 104–201 and reorganization within the U.S. Customs Service. Because notice and comment are not required by 5 U.S.C. 553(b)(B) or any other statute for these technical amendments and procedures, a regulatory flexibility analysis is not required and was not prepared for purposes of the Regulatory Flexibility Act. This rulemaking involves information collection requirements which are cleared under OMB Control No. 0625–0139 for purposes of the Paperwork Reduction Act. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number

List of Subjects in 15 CFR Part 400

Administrative practice and procedure, Confidential business information, Customs duties and inspection, Foreign-trade zones, Harbors, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 15 CFR part 400 is amended as set forth below:

PART 400—REGULATIONS OF THE FOREIGN–TRADE ZONES BOARD

1. The authority for 15 CFR part 400 continues to read as follows:

Authority: Foreign-Trade Zones Act of June 18, 1934, as amended (Pub. L. 397, 73rd Congress, 48 Stat. 998–1003 (19 U.S.C. 81a–81u)).

2. Section 400.2 is revised to read as follows:

§ 400.2 Definitions.

(a) *Act* means the Foreign-Trade Zones Act of 1934, as amended.

(b) *Board* means the Foreign-Trade Zones Board, which consists of the Secretary of the Department of Commerce (chairman) and the Secretary of the Treasury, or their designated alternates.

(c) *Customs Service* means the United States Customs Service of the Department of the Treasury.

(d) *Executive Secretary* is the Executive Secretary of the Foreign-Trade Zones Board.

(e) *Foreign-trade zone* is a restricted-access site, in or adjacent to a Customs port of entry, operated pursuant to public utility principles under the sponsorship of a corporation granted authority by the Board and under supervision of the Customs Service.

(f) *Grant of authority* is a document issued by the Board which authorizes a zone grantee to establish, operate and maintain a zone project or a subzone, subject to limitations and conditions specified in this part and in 19 CFR part 146. The authority to establish a zone includes the authority to operate and the responsibility to maintain it.

(g) *Manufacturing,* as used in this part, means activity involving the substantial transformation of a foreign article resulting in a new and different article having a different name, character, and use.

(h) *Port Director* is normally the director of Customs for the Customs jurisdictional area in which the zone is located.

(i) *Port of entry* means a port of entry in the United States, as defined by part 101 of the regulations of the Customs Service (19 CFR part 101), or a user fee airport authorized under 19 U.S.C. 58b and listed in part 122 of the regulations of the Customs Service (19 CFR part 122).

(j) *Private corporation* means any corporation, other than a public corporation, which is organized for the purpose of establishing a zone project and which is chartered for this purpose under a law of the state in which the zone is located.

(k) *Processing,* when referring to zone activity, means any activity involving a change in condition of merchandise, other than manufacturing, which results in a change in the Customs classification of an article or in its eligibility for entry for consumption.

(l) *Public corporation* means a state, a political subdivision (including a municipality) or public agency thereof, or a corporate municipal instrumentality of one or more states.

(m) *State* includes any state of the United States, the District of Columbia, and Puerto Rico.

(n) *Subzone* means a special-purpose zone established as an adjunct to a zone project for a limited purpose.

(o) *Zone* means a foreign-trade zone established under the provisions of the Act and these regulations. Where used in this part, the term also includes subzones, unless the context indicates otherwise.

(p) *Zone grantee* is the corporate recipient of a grant of authority for a zone project. Where used in this part,

the term ''grantee'' means ''zone grantee'' unless otherwise indicated.

(q) *Zone operator* is a corporation, partnership, or person that operates a zone or subzone under the terms of an agreement with the zone grantee or an intermediary entity, with the concurrence of the Port Director.

(r) *Zone project* means the zone plan, including all of the zone and subzone sites that the Board authorizes a single grantee to establish.

(s) *Zone site* means the physical location of a zone or subzone.

(t) *Zone user* is a party using a zone under agreement with the zone grantee or operator.

3. Section 400.11 is amended by revising paragraph (d)(1) to read as follows.

§ 400.11 Authority of the Board.

* * * * *

(d) *Determinations of the Board.* (1) The determination of the Board will be based on the unanimous vote of the members (or alternate members) of the Board.

* * * * *

4. Section 400.24 is amended by revising paragraph (d)(5)(i)(B) to read as follows:

§ 400.24 Application for zone.

* * * * *

(d) Exhibits. * * *

(5) Exhibit Five (Maps) shall consist of:

(i) The following maps and drawings:

* * * * *

(B) A local community map showing in red the location of the proposed zone; and

* * * * *

5. Section 400.24 is further amended by revising paragraph (h) to read as follows:

§ 400.24 Application for zone.

* * * * *

(h) *Format and number of copies.* Unless the Executive Secretary alters the requirements of this paragraph, submit an original and 8 copies of the application on 8½″ × 11″ (216 × 279 mm) paper. Exhibit Five of the original application shall contain full-sized maps, and copies shall contain letter-sized reductions.

* * * * *

6. Section 400.26 is amended by revising paragraph (a)(2) to read as follows:

§ 400.26 Application for expansion or other modification to zone project.

(a) *In general.* * * *

(2) The Executive Secretary, in consultation with the Port Director, will determine whether the proposed modification involves a major change in the zone plan and is thus subject to paragraph (b) of this section, or is minor and subject to paragraph (c) of this section. In making this determination the Executive Secretary will consider the extent to which the proposed modification would:

(i) Substantially modify the plan originally approved by the Board; or

(ii) Expand the physical dimensions of the approved zone area as related to the scope of operations envisioned in the original plan.

* * * * *

7. Section 400.27 is amended by revising paragraph (c)(3) to read as follows:

§ 400.27 Procedure for processing application.

* * * * *

(c) *Procedure—Executive Secretary responsibilities.* * * *

(3) Send copies of the filing and initiation notice and the application to the Commissioner of Customs and the Port Director, or a designee.

* * * * *

8. Section 400.27 is further amended by revising paragraph (d)(1) to read as follows:

§ 400.27 Procedure for processing application.

* * * * *

(d) *Case reviews—procedure and time schedule*—(1) *Customs review.* The Port Director, or a designee, in accordance with agency regulations and directives, will submit a technical report to the Executive Secretary within 45 days of the conclusion of the public comment period described in paragraph (c)(2) of this section.

* * * * *

9. Section 400.27 is further amended by revising paragraph (d)(2)(v)(C) to read as follows:

§ 400.27 Procedure for processing application.

* * * * *

(d) *Case reviews—procedure and time schedule*—* * *

(2) *Examiners reviews—non-manufacturing/processing.* * * *

(v) * * *

(C) The Customs adviser shall be notified when necessary for further comments, which shall be submitted within 45 days after notification.

* * * * *

§ 400.27 [Amended]

10. In § 400.27, paragraph (f)(1) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

11. In § 400.27, paragraph (f)(2) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.28 [Amended]

12. In § 400.28, paragraph (a)(1) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

13. In § 400.28, paragraph (a)(6) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.32 [Amended]

14. In § 400.32, paragraph (b)(1)(iv) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.41 [Amended]

15. In § 400.41, the third sentence is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.42 [Amended]

16. In § 400.42, paragraph (a)(1) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

17. In § 400.42, paragraph (b)(1) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

18. In § 400.42, paragraph (b)(3) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.44 [Amended]

19. In § 400.44, paragraph (b)(4) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

20. In § 400.44, paragraph (c)(3) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.45 [Amended]

21. In § 400.45, paragraph (a) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

22. In § 400.45, paragraph (b) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

23. In § 400.45, paragraph (c) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

§ 400.46 [Amended]

24. In § 400.46, paragraph (c) is amended by removing ''District Director'' where appearing therein, and adding in its place, ''Port Director''.

By order of the Foreign-Trade Zones Board, Washington, DC, this 6th day of October 1997.

Robert S. LaRussa,

Assistant Secretary of Commerce for Import Administration Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 97–27145 Filed 10–14–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 601, and 606

[Docket No. 96N–0395]

RIN 0910–AA93

Revision of the Requirements for a Responsible Head for Biological Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by deleting the requirements for a biologics establishment to name a ''responsible head'' or ''designated qualified person'' to exercise control of the establishment in all matters relating to compliance with regulatory requirements and to represent the establishment in its dealings with FDA. Because many manufacturers of biological products are firms that have more than one manufacturing location and complex corporate structures, it may no longer be practical for one individual to represent a manufacturer or possess expertise in all matters. This change will provide manufacturers with more flexibility in assigning control and oversight responsibility within a company. This final rule is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and it is intended to reduce the burden of unnecessary regulations on industry without diminishing public health protection.

EFFECTIVE DATE: October 15, 1997.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of January 29, 1997 (62 FR 4221), FDA published a proposed rule to amend the biologics regulations by deleting the requirements for a biologics establishment to name a responsible head or designated qualified person to represent the establishment in its dealings with FDA.

Under § 600.10(a) (21 CFR 600.10(a)), a manufacturer of biological products currently is required to name a responsible head who is to exercise control of the establishment in all matters relating to compliance with regulations in parts 600 through 680 (21 CFR parts 600 through 680) and who is to represent the manufacturer in all pertinent matters with the Center for Biologics Evaluation and Research (CBER). This individual must also have an understanding of the scientific principles and techniques involved in the manufacture of biological products. When FDA announced in the **Federal Register** of June 3, 1994 (59 FR 28821 and 28822), the review by CBER of certain biologics regulations to identify those regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary, § 600.10(a) was included. FDA also held a public meeting on January 26, 1995, to discuss the retrospective review effort and to provide a forum for the public to voice its comments on the retrospective review.

Many of the comments submitted requested revision or elimination of the requirements for a responsible head in § 600.10(a). The comments stated that the requirement for a responsible head to be an expert in multiple functions and to be responsible for a number of facility locations is incompatible with current industry practice. The comments added that the list of activities in § 600.10(a) is extremely broad and this regulation could be interpreted to require the responsible head to have an intimate understanding of a wide variety of extremely complex activities. All of these activities require specific expertise, and it may not be practical to expect one person to be an expert in all of those areas. Some comments addressed the requirement that the responsible head be responsible for training and have the authority to enforce discipline, stating that direct line supervision and management personnel are better qualified and in a better position to enforce or direct the enforcement of discipline and the performance of assigned functions by employees engaged in the manufacture of products. Many comments requested the designation of an alternate responsible head, especially in the situation of multiple locations.

As part of the President's ''Reinventing Government'' initiative, a report entitled ''Reinventing the Regulation of Drugs Made From Biotechnology'' was issued in November 1995. The report announced several initiatives to reduce the burden of FDA regulations on the biologics industry without reducing public health protection, including a proposal to remove the requirements in § 600.10(a) for a responsible head. The commitment to remove requirements for a responsible head was based on FDA's determination that, with the many changes that have occurred in science, technology, and corporate structure, it no longer may be practical for most biologics manufacturers to rely on one individual to meet the requirements in § 600.10(a). In addition, the responsible corporate officer doctrine, e.g., *United States* v. *Park*, 421 U.S. 658 (1975); *United States* v. *Dotterweich*, 320 U.S. 277 (1943), places the burden of ensuring compliance with the statutes and regulations applicable to biological products on corporate officials ''standing in responsible relation to a public danger.'' (*Dotterweich*, 320 U.S. at 281.) Thus, it is not necessary to require manufacturers to designate a responsible head in order to enforce the duty responsible corporate officials have to implement measures to ensure that violations do not occur. (*Park*, 421 U.S. at 672.)

In accordance with a revision to the definition of ''manufacturer'' in § 600.3 (see 61 FR 24227, May 14, 1996), an applicant may apply for and obtain a license for a biological product to be manufactured at more than one manufacturing site that may or may not be owned by the applicant. Therefore, applicants may want to designate more than one person with primary responsibility to maintain adequate oversight of multiple manufacturing sites and ensure that each is conforming to FDA's requirements for current good manufacturing practices and the applicable biologics standards. Many biologics manufacturers also manufacture drugs that are regulated by the Center for Drug Evaluation and Research (CDER) under the Federal Food, Drug, and Cosmetic Act. CDER's regulations do not contain an analogous requirement for a responsible head. FDA's proposal to revise the requirements with respect to a responsible head is an effort to harmonize CBER's and CDER's policies and requirements and to keep pace with changes in science, technology, and corporate structure.

II. Highlights of the Final Rule

Under the final rule, an authorized official may be chosen by the applicant