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.

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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

to receive and send correspondence to CBER. The applicant may choose to have more than one authorized official. Accordingly, the agency is amending § 600.10 by removing and reserving paragraph (a) and revising the heading of paragraph (b) to read ''*Personnel.*'' The agency is also amending § 601.2 *Applications for establishment and product licenses; procedures for filing* by adding the statement ''The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application'' in paragraph (a) and new paragraph (c)(6). Finally, the agency is amending § 601.25(b)(3)(VIII) by replacing ''signed by the responsible head (as defined in § 600.10 of this chapter) of the licensee'' with ''signed by an authorized official of the licensee.''

FDA is also removing § 606.20(a), which contains language similar to that in § 600.10(a) and applies to all blood establishments, including registered, unlicensed blood establishments. Like other components of the biologics industry, the blood industry has experienced changes in science, technology, and corporate structure. Complex donor and transfusion recipient issues, the evolution of sophisticated computerized laboratory and donor equipment, complicated serology problems, and state-of-the-art laboratory techniques have all contributed to changes within the structure of blood establishments, regardless of size. To ensure the quality and safety of the blood supply, many blood establishments employ personnel who are experts in donor issues, infectious disease, computers, molecular biology, serology, transfusion issues, quality control, administration, and management. It is no longer practical to expect one individual to have expertise in all the subspecialties of transfusion medicine. Accordingly, to provide sufficient flexibility for a blood establishment to select a person with appropriate training and experience to be responsible for each facet of its operation, the agency is removing and reserving § 606.20(a).

III. Comments on the Proposed Rule and FDA Responses

FDA received 11 comments on the proposed rule, which included comments from biological product manufacturers, including blood establishments. Eight of the comments fully supported the proposed rule.

Three comments received from the blood industry expressed concern that they would no longer have a single responsible head through whom they would interact with FDA, and that the responsible persons in the organization will have diminished authority and responsibility in communication and decisionmaking because their responsibilities and authority will no longer be mandated by the regulations.

FDA does not agree. In the final rule, only the requirement to retain a single responsible head is being eliminated. Any applicant wishing to have a single authorized representative who would serve the function of the responsible head as previously set forth in § 600.10(a), may do so. In the past, FDA has often encountered circumstances where the responsible head of an establishment was unable to adequately carry out her or his responsibilities in assuring that the establishment complies with FDA requirements. This failure was often due, in part, to the responsible head having inadequate knowledge in an area to determine whether FDA's requirements were being met or the responsible head was too remote in location or corporate structure to adequately monitor activities to assure requirements were being met. Removal of this requirement will allow organizations to designate responsible individuals with appropriate training and experience to provide better communication to the agency as functional experts in their respective areas of responsibility. FDA believes that the industry should have the flexibility to assign responsibility in a way that best fits each applicant's organizational structure as long as the public health protection is not diminished.

Furthermore, the elimination of the requirement for a responsible head or designated qualified person does not decrease the duty that responsible corporate officers have to ensure compliance with the law. (*Park*, and *Dotterweich*, *supra*.)

IV. Effective Date

The final rule is effective October 15, 1997. As provided under 5 U.S.C. 553(d) and § 10.40(c)(4) (21 CFR 10.40(c)(4)), the effective date of a final rule may not be less than 30 days after the date of publication, except for, among other things, ''a regulation that grants an exemption or relieves a restriction'' (§ 10.40(c)(4)(i)). Because this rule will provide greater flexibility in assigning control and oversight responsibility within a biological product establishment by eliminating the responsible head requirement, FDA believes that an immediate effective date is appropriate.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule would have no compliance costs and would not result in any new requirements. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Lists of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 600, 601, and 606 are amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

§ 600.10 [Amended]

2. Section 600.10 *Personnel* is amended by removing and reserving paragraph (a) and by revising the heading of paragraph (b) to read ''*Personnel*.''

PART 601—LICENSING

3. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; 15 U.S.C. 1451–1461.

4. Section 601.2 is amended by adding a sentence before the last sentence in the introductory text of paragraph (a) and by adding new paragraph (c)(6) to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) * * * The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. * * *

* * * * *

(c) * * *

(6) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application.

5. Section 601.25 is amended by revising the first sentence of paragraph (b)(3)(VIII) to read as follows:

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

* * * * *

(b) * * *

(3) * * *

(VIII) If the submission is by a licensee, a statement signed by an authorized official of the licensee shall be included, stating that to the best of his or her knowledge and belief, it includes all information, favorable and unfavorable, pertinent to an evaluation of the safety, effectiveness, and labeling of the product, including information derived from investigation, commercial marketing, or published literature.

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PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

6. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.20 [Amended]

7. Section 606.20 *Personnel* is amended by removing and reserving paragraph (a).

Dated: September 4, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans prescribes interest assumptions for valuing benefits under terminating single-employer plans. This final rule amends the regulation to adopt interest assumptions for plans with valuation dates in November 1997.

EFFECTIVE DATE: November 1, 1997.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (For TTY and TDD, call 800–877–8339 and request connection to 202–326–4024).

SUPPLEMENTARY INFORMATION: The PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions for valuing plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

Among the actuarial assumptions prescribed in part 4044 are interest assumptions. These interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Two sets of interest assumptions are prescribed, one set for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. This amendment adds to appendix B to part 4044 the annuity and lump sum interest assumptions for valuing benefits in plans with valuation dates during November 1997.

For annuity benefits, the interest assumptions will be 5.70 percent for the first 25 years following the valuation date and 5.00 percent thereafter. The annuity interest assumptions represent a decrease (from those in effect for October 1997) of 0.20 percent for the first 25 years following the valuation date and are otherwise unchanged. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. The lump sum interest assumptions represent a decrease (from those in effect for October 1997) of 0.25 percent for the period during which a benefit is in pay status; they are otherwise unchanged.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans with valuation dates during November 1997, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.