

**B. Environmental Impact**

The agency has determined under 21 CFR 25.31(h) 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.

**C. Federalism**

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

**V. Paperwork Reduction Act of 1995**

This direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

**VI. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this direct final rule. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 600**

Biologics, 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 part 600 is 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 in paragraph (c)(3) by removing the words “spore-bearing” and adding in their place the words “spore-forming”.

■ 3. Section 600.11 is amended in paragraph (e)(1) by removing the words “spore-bearing” and adding in their place the words “spore-forming”; in paragraph (e)(2) by removing the words “spore-bearing” in the heading and text, and adding in their place the words “spore-forming”; and by revising paragraph (e)(3) to read as follows:

**§ 600.11 Physical establishment, equipment, animals, and care.**

\* \* \* \* \*

(e) \* \* \*

(3) *Work with spore-forming microorganisms.* (i) Manufacturing processes using spore-forming microorganisms conducted in a multiproduct manufacturing site must be performed under appropriate controls to prevent contamination of other products and areas within the site. Prevention of spore contamination can be achieved by using a separate dedicated building or by using process containment if manufacturing is conducted in a multiproduct manufacturing building. All product and personnel movement between the area where the spore-forming microorganisms are manufactured and other manufacturing areas must be conducted under conditions that will prevent the introduction of spores into other areas of the facility.

(ii) If process containment is employed in a multiproduct manufacturing area, procedures must be in place to demonstrate adequate removal of the spore-forming microorganism(s) from the manufacturing area for subsequent manufacture of other products. These procedures must provide for adequate removal or decontamination of the spore-forming microorganisms on and within manufacturing equipment, facilities, and ancillary room items as well as the removal of disposable or product dedicated items from the manufacturing area. Environmental monitoring specific for the spore-forming microorganism(s) must be conducted in adjacent areas during manufacturing operations and in the manufacturing area after completion of cleaning and decontamination.

\* \* \* \* \*

Dated: December 11, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[TD 9101]

**RIN 1545–BC79**

**Information Reporting Relating to Taxable Stock Transactions**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations requiring information reporting by a corporation if control of the corporation is acquired or if the corporation has a recapitalization or other substantial change in capital structure. This document also contains temporary regulations concerning information reporting requirements for brokers with respect to transactions described in section 6043(c). The text of these temporary regulations also serves as the text of proposed regulations set forth in the Proposed Rules section of this issue of the **Federal Register**.

**DATES:** *Effective Date:* These regulations are effective December 30, 2003.

*Applicability Dates:* For dates of applicability, see §§ 1.6043–4T(i) and 1.6045–3T(g).

**FOR FURTHER INFORMATION CONTACT:** Nancy Rose at (202) 622–4910 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Paperwork Reduction Act**

The forms referenced in these regulations have been, or will be, reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books and records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.