What Is the Unsafe Condition Presented in This AD?

(d) The actions specified in this AD are intended to prevent interrogating aircraft from possibly receiving inaccurate replies, due to suppression, from aircraft equipped with the GTX 330/330D Mode S Transponders when the pulses are below the Minimum Trigger Level (MTL). The inaccurate replies could result in reduced vertical separation or unsafe TCAS resolution advisories.

What Must I Do To Address This Problem?

(e) To address this problem, you must accomplish the following:

Action	Compliance	Procedures
Install GTX 330/330D software upgrade to version 3.03.	Install the software upgrade within 30 days after the effective date of this AD, unless already accomplished.	Follow GARMIN International Inc. Service Bulletin No.: 0304, Rev B, dated June 12, 2003.

How Do I Get Copies of the Documents Referenced in This AD?

(g) You may get copies of the documents referenced in this AD from GARMIN International Inc. 1200 East 151st Street, Olathe, KS 66062. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on December 19, 2003.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–31978 Filed 12–29–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. 2003N–0528]

Revision of the Requirements For Spore-Forming Microorganisms; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. FDA is proposing this amendment due to advances in facility, system, and equipment design and in sterilization technologies that would allow work with spore-forming microorganisms to be performed in multiproduct manufacturing areas. We are amending the regulations because the existing requirement for always using separate, dedicated facilities and equipment for work with spore forming microorganisms is no longer necessary. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. We are taking this action because the proposed changes are noncontroversial and we do not anticipate any significant adverse comments. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

DATES: Submit written comments on or before March 15, 2004.

ADDRESSES: Submit written or electronic comments on the proposed rule to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion rule will also be considered as comments regarding the direct final rule. We are publishing the direct final rule because the rule contains noncontroversial changes, and we do not anticipate that it will receive any significant adverse comments.

An adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not subjects of significant adverse comments.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document, before the effective date of the direct final rule, confirming that the direct final rule will go into effect on June 1, 2004. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

Spore-forming microorganisms are used in the production of certain biological products. These microorganisms may be used as source material for further manufacture into final products used in the prevention, treatment or cure of a disease or condition of human beings. By their very nature, these microorganisms pose a great challenge to manufacturers. Bacteria produce spores as a means to survive adverse environmental

conditions, while some fungi use them as a form of reproduction. Spores show great resistance to high temperature, freezing, dryness, antibacterial agents, radiation, and toxic chemicals. Under favorable conditions, spores can germinate into actively growing bacteria and fungi. Many of these spore-forming microorganisms are pathogenic to humans and have been implicated in causing morbidity and mortality. To ensure the safety of a biological product manufactured in a facility in which spore-forming microorganisms are present, these microorganisms must be kept under tight control to avoid the release of spores into the manufacturing atmosphere and potential contamination of other products.

Due to the unique survival properties of spore-forming microorganisms, current FDA regulations require that work with these microorganisms be conducted separately from manufacturing operations for other products. (Currently, FDA regulations use the term ''spore-bearing'' microorganisms. In this rulemaking, we are proposing to revise these regulations to use the term ''spore-forming'' because it is a more commonly used term. For the purposes of these regulations, spore-forming microorganisms include both the spore and vegetative cells.) Under § 600.11(e)(3) (21 CFR 600.11(e)(3)), all work with spore-forming microorganisms must be performed in an entirely separate building, or in a completely walled-off portion of a building if that portion is constructed so as to prevent contamination of other areas and if entrances to such portion are independent of the remainder of the building. Section 600.11(e)(3) further requires that all vessels, apparatus, and equipment used for spore-forming microorganisms be permanently identified and reserved exclusively for use with those organisms. This provision also states that any materials destined for further manufacturing may be removed from this area only under conditions that will prevent the introduction of spores into other manufacturing areas.

In accordance with Executive Order 12866, which directs Federal agencies to review their regulations and eliminate or modify those that are outdated or otherwise in need of reform, we are revising § 600.11(e)(3) to allow greater manufacturing flexibility regarding work with spore-forming microorganisms. The revisions provide that work with spore-forming microorganisms may be performed in multiproduct manufacturing areas when appropriate controls to prevent contamination of other products and areas exist. We recognize that advances in facility, system, and equipment design and in sterilization technologies have increased the ability of manufacturers to control and analyze the manufacture of biological products and the equipment used in their manufacture. The use of appropriate controls and procedures and processes provide an adequate degree of confidence that a product meets the expected levels of safety and purity. Areas of special concern, such as containment, contamination with pathogenic and/or toxic agents, sterilization, and disinfection can be addressed using currently available and required procedures and processes.

This proposed rule does not apply to spore-forming microorganisms used for testing of biological products to determine the growth-promoting qualities of test media used to ensure the sterility of each lot of product or as biological indicators for validation of steam sterilization cycles. The rule also does not change the requirements for those products set forth in § 600.11(e)(2) and 21 CFR 610.12.

II. Highlights of the Proposed Rule

We are proposing to amend our regulations involving spore-forming microorganisms as set forth below.

A. Work With Spore-Forming Microorganisms

We are revising § 600.11(e)(3) to provide greater flexibility in production facilities and procedures for work with spore-forming microorganisms.

Revised § 600.11(e)(3)(i) states that 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. We regard a manufacturing site as an entire complex of buildings, connected or separate, that belongs to one entity engaged in the manufacture of any one product or multiple products. An area within a manufacturing site is a specified location within a facility (physical structure) associated with the manufacturing of any one product or multiple products. Revised § 600.11(e)(3)(i) further states that prevention of spore contamination can be achieved by using a separate, dedicated building or, if manufacturing is conducted in a multiproduct manufacturing building, by using process containment. Finally, revised § 600.11(e)(3)(i) states that 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.

Revised § 600.11(e)(3)(ii) states that 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. Revised § 600.11(e)(3)(ii) further states that 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. Finally, revised § 600.11(e)(3)(ii) states that 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.

Under revised § 600.11(e)(3(ii), processing and propagation of spore-forming microorganisms must be conducted in areas and using systems that are not used for any other purpose at the same time. Prior to processing and propagation of any organism, procedures must be designed and in place to prevent contamination with pathogenic and/or toxic agents, as well as to decontaminate, sterilize and/or disinfect, as appropriate, all affected areas and systems. It is important to demonstrate control over and containment of spore-forming microorganisms during their propagation and processing in order to prevent contamination of the product. Products derived from spore-forming microorganisms should not be removed from designated areas unless this can be done in a manner that prevents contamination of other products. These containment procedures will provide a level of assurance that products made using spore-forming microorganism remain safe, pure, and of high quality.

The agency anticipates developing a guidance document to assist manufacturers in complying with these more flexible provisions on work with spore-forming microorganisms.

B. Substitution of ''Spore-Forming'' for ''Spore-Bearing''

As noted previously in this document, we are replacing the term ''spore-bearing'' in our regulations with the term ''spore-forming'' because the latter has become the more commonly used term to describe these microorganisms.

Accordingly, in addition to § 600.11(e)(3), we are revising §§ 600.10(c)(3) (21 CFR 600.10(c)(3)) and 600.11(e)(1) and (e)(2) by substituting the term ''spore-forming'' for the term ''spore-bearing''.

III. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). We believe that this proposal is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant economic impact on a substantial number of small entities. Because the proposed rule allows for greater flexibility in production facilities and procedures for work with spore-forming microorganisms, it would not result in any increased burden or costs on small entities. Therefore, FDA certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities, and no further analysis is required under the Regulatory Flexibility Act.

The Unfunded Mandates Reform Act requires that agencies prepare a written statement under section 202(a) of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). Because the rule does not impose mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

B. Environmental Impact

The agency 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 proposed 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.

IV. The Paperwork Reduction Act of 1995

This proposed 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.

V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposal. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed 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, it is proposed that 21 CFR part 600 be 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.

[FR Doc. 03–31918 Filed 12–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–143321–02; REG–156232–03]

RIN 1545–BB60; RIN 1545–BC80

Information Reporting Relating to Taxable Stock Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of previous proposed rules; notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: This document withdraws proposed regulations published in the **Federal Register** on November 18, 2002 (REG–143321–02). In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to information reporting relating to taxable stock transactions. This document contains proposed regulations under section 6043(c) 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 proposed regulations under section 6045 concerning information reporting requirements for brokers with respect to transactions described in section 6043(c). The text of the temporary regulations serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by March 29, 2004. Outlines of topics to be discussed at the public hearing scheduled for March 31, 2004, at 10 a.m., must be received by March 10, 2004.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–156232–03), room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–156232–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at www.irs.gov/regs. The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Nancy L. Rose (202) 622–4910; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Robin Jones at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The forms referenced in these regulations have been, or will be, 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.

Background

This document withdraws the Notice of Proposed Rulemaking (REG–143321–02) that was published in the **Federal Register** on November 18, 2002 (67 FR 65496). Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR Part 1) relating to sections 6043 and 6045. The temporary regulations set forth information reporting requirements relating to acquisitions of control and substantial changes in capital structure. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments and these proposed regulations.

On November 18, 2002, the IRS published temporary regulations under section 6043(c) (TD 9022). The transactions covered by the reporting requirement were certain acquisitions of control and substantial changes in the capital structure of a corporation. These regulations required a corporation to attach a form to its income tax return describing these transactions and to file information returns with respect to certain shareholders in such transactions. On November 18, 2002, the IRS also published temporary regulations under section 6045, which provided for information reporting with respect to these transactions by brokers (together with the section 6043(c) temporary regulations, the ''2002 temporary regulations''. The 2002 temporary regulations were effective for acquisitions of control and substantial changes in capital structure occurring after December 31, 2001, if the reporting corporation or any shareholder was required to recognize gain (if any) as a result of the application of section 367(a) as a result of the transaction.

The text of the 2002 temporary regulations also served as the text of proposed regulations set forth in a cross-referencing notice of proposed rulemaking published in the Proposed Rules section of the same issue of the **Federal Register** (2002 proposed regulations) (REG–143321–02). The provisions of the proposed regulations were proposed to be effective with respect to any acquisition of control or substantial change in capital structure occurring after the date on which final regulations would be published in the **Federal Register**. The preamble to the notice of proposed rulemaking invited public comments with respect to the potential for duplicate reporting and with respect to the burden of compliance with the reporting requirements.

The IRS received a number of written public comments with respect to the information reporting requirements set forth in the 2002 temporary and proposed regulations. In addition, the IRS met with representatives of the Information Reporting Program Advisory Committee (IRPAC) and other representatives of the securities industry to discuss their concerns and suggestions for revisions to the regulations.

After considering the issues concerning affected taxpayers, the IRS has decided to revise the 2002 temporary regulations. The revised temporary regulations set forth information reporting rules that will help ensure that brokers and shareholders receive information regarding these corporate transactions, without unduly burdening brokers and other members of the securities industry. The text of the revised