

*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.*

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## 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and to revise outdated regulations without diminishing public health protection.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