List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Pratt & Whitney: Docket No. 98–ANE–71-AD.

Applicability: JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A,–11, –15, –15A, –17, –17A, –17R, and –17AR series turbofan engines with 2nd stage compressor disks, part number (P/N) 745902, P/N 790832, and P/N 807502, installed. These engines are installed on, but not limited to Boeing 727 series airplanes, Boeing 737–100 and –200 series airplanes and McDonnell Douglas DC–9 series airplanes.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a rupture of the 2nd stage compressor disk, caused by machining damage, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

Removal of Disk

(a) Remove from service 2nd stage compressor disks, P/N 745902, P/N 790832, and P/N 807502, identified by serial number in the Accomplishment Instructions of JT8D Alert Service Bulletin (ASB) JT8D A6336, Revision 1, dated June 29, 1999, prior to accumulating 2,000 cycles since new.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(c) Special flight permits may be issued in accordance with 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on December 5, 2000.

Diane S. Romanosky,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 00–31614 Filed 12–11–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 660

[Docket No. 00N–1586]

Revision to Requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents; 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 applicable to microbiological controls for licensed Anti-Human Globulin (AHG) and Blood Grouping Reagents (BGR). FDA is proposing to remove the requirements that the products be sterile. FDA is taking this action because the requirement that these products be sterile is not necessary for the products to be safe, pure, and potent. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. FDA is taking this action final because the proposed changes are noncontroversial and FDA anticipates that it will receive no significant adverse comment.

DATES: Submit written comments on or before February 26, 2001.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, 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. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment.

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, FDA 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, FDA 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, FDA 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 11, 2001. Additional information about FDA's direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21,1997 (62 FR 62466).

AHG and BGR are used primarily for testing human blood for the detection of red cell antigens and antibodies. As defined in 21 CFR 660.20, BGR is a product that comes from blood, plasma, serum, or protein-rich fluids and consists of an antibody-containing fluid containing one or more of the blood grouping antibodies listed in 21 CFR 660.28(d). Under 21 CFR 660.50, AHG is a serum or protein-rich fluid that consists of one or more antiglobulin antibodies identified in 21 CFR 660.55(d). AHG and BGR are biological products as defined in section 351 of the Public Health Service Act (42 U.S.C 262) (the PHS Act). These products are also devices, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321), and fall within the definition of in vitro diagnostic products in § 809.3(a) (21 CFR 809.3(a)).

AHG and BGR must meet the licensing requirements of section 351 of the PHS Act and the regulations in parts 600 through 660 (21 CFR parts 600 through 660). Section 351 of the PHS Act requires that a license applicant demonstrate that the biological product that is the subject of the application is safe, pure, and potent, and that the manufacturing facilities are designed to ensure that the biological product continues to be safe, pure, and potent.

AHG and BGR are also medical devices and in vitro diagnostic products as defined in § 809.3(a), and therefore are subject under the act and 21 CFR 809.20(b) to the requirements in the Quality System Regulation (QSR) in part 820 (21 CFR part 820). The QSR requires that a manufacturer establish appropriate manufacturing controls. A manufacturer must validate the manufacturing process in accordance with § 820.75 and establish production and process controls (§ 820.70). See also the ''Guideline for the Manufacture of In Vitro Diagnostic Products'' published in the **Federal Register** of January 10, 1994 (59 FR 1402).

The standards for AHG and BGR were established by final rules published in the **Federal Register** of February 11, 1985, and April 19, 1988, respectively (50 FR 5574 and 53 FR 12760). The standards in §§ 660.20(a) and 660.50(a) require BGR and AHG to be manufactured by a ''method demonstrated to consistently yield a sterile product.'' In addition, the requirements for processing methods of BGR and AHG under §§ 660.21(a)(2) and 660.51(a)(3) state ''[o]nly that material that has been fully processed, thoroughly mixed in a single vessel, and sterile filtered shall constitute a lot,'' and under §§ 660.21(a)(3) and 660.51(a)(4) that ''[a] lot may be subdivided into clean sterile vessels''.

When the regulations were codified, the agency expected that AHG and BGR would be manufactured as sterile under the conditions understood at that time. The agency also considered that the process of sterile filtration and a sterile container and closure system, e.g., vessels, would be sufficient to yield consistently a sterile product (50 FR 5574 at 5575; 53 FR 12760 at 12761). However, current good manufacturing practices require aseptic processing controls to be in place in order to ensure a sterile product. The agency considers AHG and BGR to be microbiologically controlled in vitro diagnostics (IVD's), which are IVD's that are capable of supporting microorganism life and growth and may contain certain levels of microorganisms. Microbiologically controlled IVD's do not need to be manufactured under aseptic conditions; however, they should be manufactured under conditions such that the microbial level will not adversely impact product performance. Manufacturers must establish specifications for these products through testing and validation. FDA's proposed revision of the regulations would in no way undermine the safety, potency, or purity of the products. The proposed revisions would also not prevent a manufacturer from implementing aseptic processing controls for manufacturing AHG and BGR, if the manufacturer determines such controls are appropriate for its product. Therefore, the agency is proposing to revise the standards for AHG and BGR to remove the requirement that these products be sterile.

II. Highlights of the Proposed Rule

FDA is proposing to amend the biologics regulations by revising §§ 660.20, 660.21, 660.50, and 660.51 to clarify the agency's requirements with regard to microbiological control in manufacturing AHG and BGR. FDA is proposing to amend the regulations by deleting all references to sterile processing techniques such as sterile filtration and sterile container and closure systems. FDA is proposing to amend §§ 660.20(a) and 660.50(a) by deleting the phrase regarding preparation ''by a method demonstrated to yield consistently a sterile product'' because FDA recognizes that controls to ensure a sterile product, i.e., aseptic processing controls, are not necessary to ensure that AHG and BGR meet their performance specifications. In addition, §§ 660.21(a)(1) and 660.51(a)(1) include requirements regarding the adequacy of the processing method. FDA is proposing to amend §§ 660.21(a)(2) and 660.51(a)(3) by deleting the term ''sterile'' because the manufacturer must establish those controls appropriate for its product, and it may not be necessary for microbiologically controlled IVD's to undergo sterile filtration. FDA is proposing to amend §§ 660.21(a)(3) and 660.51(a)(4) by deleting the reference to ''clean, sterile vessels'' because FDA believes that manufacturers are in the best position to determine the appropriate level of microbial control for container and closure systems. Appropriate process specifications must be established by the manufacturer to ensure that microbiologically controlled IVD's are manufactured under appropriate conditions and controls resulting in a product that consistently meets all of its specifications. The manufacturer must demonstrate in the license application that the appropriate level of control of microbial contamination ensures that the biological product continues to meet the licensing requirements. The proposed change to the regulation in no way affects the testing and validation a manufacturer must perform in order to establish that the manufacturing specifications are appropriate to ensure the product will perform as intended. In addition, under the current good manufacturing practice regulations for blood and blood components, end users of AHG and BGR, such as blood banks, are required under § 606.65(c) to perform daily checks for potency and specificity of supplies and reagents used in the collection and testing of blood and blood components.

The agency also believes the proposed change is consistent with other requirements in the biologics regulations, such as the sterility testing requirements set forth in § 610.12. This section requires sterility testing for most biological products; however, BGR and AHG are specifically exempted from the sterility testing requirements for bulk and final container material § 610.12(g)(4)).

The proposed rule would also remove the requirement in § 660.51(a)(4) that a manufacturer who subdivides a lot shall include this information on the protocol. FDA is making this change to reflect current agency practice. Manufacturers would still be required to submit this information in the license application. See § 601.2 regarding

requirements for the submission of samples and protocols to FDA.

III. Analysis of Impacts

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

FDA has examined the impact of the proposed rule under Executive Order 12866 and 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; distribute impact; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This proposed rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small business entities. Because the proposed rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the proposed rule will not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. This proposed rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act of 1995 because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any one year.

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.

IV. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget 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 Dockets Management Branch (address above) written comments regarding this proposal by February 26, 2001. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 660 be amended as follows:

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

1. The authority citation for 21 CFR part 660 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263 263a, 264.

§ 660.20 [Amended]

2. Section 660.20 *Blood Grouping Reagent* is amended in paragraph (a) by removing the words ''prepared by a method demonstrated to yield consistently a sterile product and''.

§ 660.21 [Amended]

3. Section 660.21 *Processing* is amended in paragraph (a)(2) by removing the word ''sterile''; and in paragraph (a)(3) by removing the words ''clean, sterile vessels. Each subdivision shall constitute a sublot.'' and adding in its place the word ''sublots.''

§ 660.50 [Amended]

4. Section 660.50 *Anti-Human Globulin* is amended in paragraph (a) by removing the words ''and be prepared by a method demonstrated to yield consistently a sterile product''.

§ 660.51 [Amended]

5. Section 660.51 *Processing* is amended in the first sentence of paragraph (a)(3) by removing the word ''sterile'' and in paragraph (a)(4) by removing the words ''clean, sterile vessels. Each subdivision shall constitute a sublot'' and adding in its place the word ''sublots'', and in the third sentence by removing the words ''and on the protocol''.

Dated: December 3, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31587 Filed 12–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 945

[FHWA Docket No. FHWA–99–5844]

RIN 2125–AE63

Dedicated Short Range Communications in Intelligent Transportation Systems (ITS) Commercial Vehicle Operations

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of docket comment period.

SUMMARY: This document reopens the comment period on this docket and delays the issuance of a final rule to require the use of the FHWA specification for Dedicated Short Range Communication (DSRC) for Commercial Vehicle Operations (CVO); a provisional standard for Intelligent Transportation Systems (ITS) commercial vehicle projects using highway trust funds. Based on the comments received, the date of the final rule will be determined by the completion of the testing program to evaluate products designed to meet the provisional standard. Also, this document responds to all the substantive comments received to date on this docket.

DATES: This docket will remain open until the FHWA publishes another rulemaking document when testing is complete.

ADDRESSES: Mail or hand deliver comments to the docket number that appears in the heading of this document to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590, or submit electronically at *http://dmses.dot.gov/submit.* All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page