

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006-23-13 BAE Systems (Operations) Limited (Formerly British Aerospace

Regional Aircraft): Amendment 39-14825. Docket No. FAA-2006-25337; Directorate Identifier 2006-NM-138-AD.

Effective Date

- (a) This AD becomes effective December 18, 2006.

Affected ADs

- (b) None.

Applicability

- (c) This AD applies to all BAE Systems (Operations) Limited Model BAe 146-100A, -200A, and -300A series airplanes, certificated in any category.

Unsafe Condition

- (d) This AD results from reports of three-phase circuit breakers overheating on in-service airplanes. We are issuing this AD to prevent failure of a three-phase circuit breaker. Such failure could prevent an electrical load from being isolated from its electrical supply, which could result in smoke or fire in the flight deck.

Compliance

- (e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Detailed Inspection and Corrective Actions

- (f) Within 12 months after the effective date of this AD, do a detailed inspection of the three-phase circuit breakers and three-phase circuit breaker panels for discrepancies (including but not limited to physical damage, cracks, deterioration, corrosion, discoloration, contamination by foreign objects, and missing or improperly installed terminal connections or attachments), in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.24-141, dated August 15, 2005. If any discrepancy is found, before further flight, fix the discrepancy and replace unserviceable units with new units, as applicable, in accordance with the inspection service bulletin.

Note 1: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

No Reporting

- (g) Although the inspection service bulletin referenced in this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

- (h)(1) The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

- (2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

- (i) The European Aviation Safety Agency airworthiness directive 2006-0132, dated May 18, 2006, also addresses the subject of this AD.

Material Incorporated by Reference

- (j) You must use BAE Systems (Operations) Limited Inspection Service Bulletin ISB.24-141, dated August 15, 2005, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL-401, Nassif Building, Washington, DC; on the Internet at <http://dms.dot.gov>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on October 31, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6-18966 Filed 11-9-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. 1992N-0297 (formerly 92N-0297)]

RIN 0905-AC81

Distribution of Blood Derivatives by Registered Blood Establishments That Qualify as Health Care Entities; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Delay of Applicability Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of applicability date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until December 1, 2008, the applicability date of a certain

requirement of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720) (the final rule). The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The provisions of the final rule became effective on December 4, 2000, except for certain provisions whose effective or applicability dates were delayed in five subsequent **Federal Register** notices, until December 1, 2006. The provision with the delayed applicability date would prohibit wholesale distribution of blood derivatives by registered blood establishments that meet the definition of a "health care entity." In the **Federal Register** of February 1, 2006 (71 FR 5200), FDA published a proposed rule specific to the distribution of blood derivatives by registered blood establishments that qualify as health care entities (the proposed rule). The proposed rule would amend certain limited provisions of the final rule to allow certain registered blood establishments that qualify as health care entities to distribute blood derivatives. In response to the proposed rule, FDA received substantive comments.

As explained in the **SUPPLEMENTARY INFORMATION** section of this document, further delaying the applicability of § 203.3(q) (21 CFR 203.3(q)) to the wholesale distribution of blood derivatives by health care entities is necessary to give the agency additional time to address comments on the proposed rule, consider whether regulatory changes are appropriate, and, if so, to initiate such changes.

DATES: The applicability date for § 203.3(q) to the wholesale distribution of blood derivatives by health care entities is delayed until December 1, 2008.

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, 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: The PDMA (Pub. L. 100-293) was enacted on April 22, 1988, and was modified by the PDA (Pub. L. 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified, amended the Federal Food, Drug, and Cosmetic Act (the act) to, among other things, prohibit, with certain exceptions, the sale, purchase, or trade (or offer to sell, purchase, or trade) of prescription drugs that were

purchased by hospitals or other health care entities (section 503(c)(3)(A)(ii)(I) of the act (21 U.S.C. 353(c)(3)(A)(ii)(I))). Section 503(c)(3) of the act also states that "[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law * * *."

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720) that were to take effect on December 4, 2000. Most of the provisions of the final rule took effect on this date. Certain provisions of the final rule, including § 203.3(q) which defines the term "health care entity," were delayed on account of concerns raised by the affected parties. The agency received several letters on, and held several meetings to discuss, the implications of the final rule for blood centers that distribute blood derivative products and provide health care to hospitals and patients. Under the final rule as written, blood establishments functioning as health care entities would not be allowed to engage in wholesale distribution of prescription drugs except for blood and blood components intended for transfusion, which are exempted from the regulations under § 203.1. As discussed in the preamble to the final rule (64 FR 67720 at 67725 to 67727), blood derivatives are not blood components. Therefore, under the final rule as written, registered blood establishments that qualify as health care entities could not distribute blood derivatives. Based on comments from interested parties, FDA decided to delay the applicability of § 203.3(q), until October 1, 2001, and reopened the administrative record to give interested persons until July 3, 2000, to submit written comments on this provision (65 FR 25639, May 3, 2000).

FDA has delayed the applicability date of § 203.3(q) four more times, most recently until December 1, 2006. On these occasions, the applicability date was delayed to give the agency time to consider whether regulatory changes were warranted (66 FR 12850, March 1, 2001; 67 FR 6645, February 13, 2002; 68 FR 4912, January 31, 2003; 69 FR 8105, February 23, 2004). In the **Federal Register** of February 1, 2006 (71 FR 5200), FDA issued a proposed rule that would amend the final rule to allow certain registered blood establishments that qualify as health care entities to distribute blood derivatives. FDA has received substantive comments on the proposed rule from affected parties. Today, FDA is further delaying the applicability of § 203.3(q) to the

wholesale distribution of blood derivatives by health care entities to give FDA additional time to address comments on the proposed rule and consider the appropriate regulatory changes.

FDA has examined the impacts of this delay of the applicability date under Executive Order 12866. 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 action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry by delaying the applicability of § 203.3(q) to the wholesale distribution of blood derivatives by health care entities while FDA continues to address comments on the proposed rule and consider regulatory changes. Thus, this action is not a significant action as defined by the Executive order.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. Given the imminence of the current December 1, 2006, compliance date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the applicability date is in the public interest.

Dated: October 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-18892 Filed 11-9-06; 8:45 am]

BILLING CODE 4160-01-S