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 failure of a remote control circuit breaker (RCCB) to trip during an overload condition due to a defective braze joint in the RCCB latch assembly, which could result in overheating of the RCCB load wire, and consequent smoke and possible fire in the electrical/electronic (E/E) compartment of the airplane, accomplish the following:

Inspection and Replacement, If Necessary

(a) Within 6 months after the effective date of this AD, perform a one-time inspection of the single-phase RCCB or RCCBs, as applicable, at station Y=120.050 in the E/E compartment of the airplane to determine the part number and serial number of the RCCB(s), per the Accomplishment Instructions of McDonnell Douglas Alert Service Bulletin MD90–24A053, Revision 01, excluding Evaluation Form, dated February 23, 2001.

(1) If an RCCB has a part number that is not listed in Table 1, Figure 1, or Table 2, Figure 2, of the service bulletin, as applicable: No further action is required by this AD for that RCCB. It is not necessary to report findings to Boeing by completing the form in the Appendix of the service bulletin.

(2) If an RCCB has a part number that is listed in Table 1, Figure 1, or Table 2, Figure 2, of the service bulletin, as applicable, and the corresponding serial number is not identified in that table: No further action is required by this AD for that RCCB. It is not necessary to report findings to Boeing by completing the form in the Appendix of the service bulletin.

(3) If an RCCB has a part number that is listed in Table 1, Figure 1, or Table 2, Figure 2, of the service bulletin, as applicable; and the corresponding serial number is identified in that table: Before further flight, replace the RCCB with a new or serviceable RCCB per the Accomplishment Instructions of the service bulletin. The replacement RCCB must have the same part number as the part being replaced, and a serial number that is not identified in Table 1, Figure 1, or Table 2, Figure 2, of the service bulletin, as applicable. It is not necessary to report findings to Boeing by completing the form in the Appendix of the service bulletin.

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, Los Angeles Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permits

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

Incorporation by Reference

(d) The actions shall be done in accordance with McDonnell Douglas Alert Service Bulletin MD90–24A053, Revision 01, excluding Evaluation Form, dated February 23, 2001. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(e) This amendment becomes effective on March 7, 2003.

Issued in Renton, Washington, on January 22, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–1953 Filed 1–30–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. 92N–0297]

RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until April 1, 2004, the effective date of certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a ''health care entity'' in the final rule. The agency further delayed the effective date of these requirements in two subsequent **Federal Register** documents. Most recently, in the **Federal Register** of February 13, 2002 (67 FR 6645), FDA delayed the effective date until April 1, 2003. This action further delays the effective date of these requirements until April 1, 2004. 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 agency is taking this action to address concerns about the requirements raised by affected parties.

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)(3)(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)(3)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. As explained in the **SUPPLEMENTARY INFORMATION** section, FDA has prepared a report for Congress and concluded that although FDA can address some of industry's concerns with the PDMA regulation through regulatory changes, other concerns would have to be addressed by Congress through legislative action. The further delay is necessary to give Congress additional time to consider the information and conclusions contained in the agency's report, and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

DATES: The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until April 1, 2004. Submit written or electronic comments by April 1, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, and 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs and for the distribution of blood derived prescription drug products by health care entities.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing PDMA (64 FR 67720). After publication of the final rule, the agency received communications from industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. On March 29, 2000, the agency met with representatives from the wholesale drug industry and industry associations to discuss their concerns. In addition, FDA received a petition requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition from the Small Business Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the communications regarding wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care to hospitals and patients.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency published a notice in the **Federal Register** of May 3, 2000 (65 FR 25639), delaying the effective date for those provisions until October 1, 2001. In addition, the May 2000 document delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001. The May 2000 document also reopened the administrative record to give interested persons until July 3, 2000, to submit written comments.

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106–619) that it supported the ''recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments.'' In addition, the Committee stated that it ''believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry.'' The Committee directed the agency to provide a report to the Committee summarizing the comments and issues raised and agency plans to address the concerns.

After issuing the delay of the effective date, the agency announced in the **Federal Register** of September 19, 2000 (65 FR 56480), that a public hearing would be held to discuss the requirements at issue. The hearing was held on October 27, 2000, and comments were accepted until November 20, 2000.

In the **Federal Register** of March 1, 2001 (66 FR 12850), the agency announced that it was further delaying, until April 1, 2002, the effective date of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. As explained by the agency, the effective date was further delayed to give FDA additional time to consider comments and testimony received, for FDA to prepare its report to Congress, and, if appropriate, for Congress or the agency to make legislative or regulatory changes. The report was completed and submitted to Congress on June 7, 2001.

In its report to Congress, the agency concluded that it could address some, but not all, of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, to make other changes requested by the secondary wholesale industry, Congress would have to amend section 503(e) of the act. As a result, on February 13, 2002, FDA further delayed the effective date of the relevant provisions of the final rule until April 1, 2003, in part to give Congress time to consider the information and conclusions contained in the agency's report and to determine if legislative action was appropriate. Based on a recent petition submitted by affected parties, FDA understands that members of Congress are, in fact, considering the issues presented in the agency's report. Due to competing legislative priorities, however, the issues have not yet been resolved. Therefore, to give Congress additional time to determine if legislative action is appropriate, the agency is further delaying the effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. The further delay of the effective date until April 1, 2004, will also give the agency additional time to consider whether regulatory changes are warranted.

FDA has examined the impacts of this delay of effective 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 effect of §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities while Congress considers taking legislative action. Thus, this action is not a significant action as defined by the Executive order.

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 effective date is in the public interest.

Dated: January 23, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2293 Filed 1–30–03; 8:45 am]

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