

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.

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