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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. 1992N–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 December 1, 2006, 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 three subsequent **Federal Register** notices. Most recently, in the **Federal Register** of January 31, 2003 (68 FR 4912), FDA delayed the effective date until April 1, 2004. This action further delays the effective date of these requirements until December 1, 2006. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of

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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 in the final rule raised by affected parties.

As explained in the **SUPPLEMENTARY INFORMATION** section, FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that will generate a de facto electronic pedigree, including prior transaction history back to the original manufacturer, as a routine course of business. If this technology is widely adopted, it is expected to help fulfill the pedigree requirements of the PDMA and obviate or resolve many of the concerns that have been raised with respect to the final rule by ensuring that an electronic pedigree travels with a drug product at all times. Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2007 to allow stakeholders time to continue to move toward this goal. In addition, the further delay of the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities is necessary to 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 December 1, 2006. Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (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, 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) that were to take effect on December 4, 2000. 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. Respectively, these provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" and set forth requirements regarding an "identifying statement" (commonly referred to as a "pedigree").

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 delayed the effective date for those provisions until October 1, 2001 (65 FR 25639). FDA also delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001, and reopened the administrative record to give interested persons until July 3, 2000, to submit written comments. The rest of the regulations took effect on December 4, 2000.

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." The Committee further 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.

On March 1, 2001, FDA again delayed the effective dates of the provisions to allow time for the agency to consider the comments and testimony received at an October 27, 2000, public hearing and to prepare its report to Congress (65 FR 56480). The agency's report, which was submitted to Congress on June 7, 2001, concluded that FDA could address some 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.

Since submitting its report to Congress, FDA has delayed the effective date of the provisions two more times, most recently until April 1, 2004. On both occasions, the effective date was delayed in order to give Congress additional time to determine whether legislative action was appropriate and to give the agency time to consider whether regulatory changes were warranted (67 FR 6645; 68 FR 4912).

Today, the agency is further delaying, until December 1, 2006, 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. The agency's decision to delay the effective date of §§ 203.3(u) and 203.5 was based, in part, on comments received on FDA's Counterfeit Drug Task Force's Interim Report (Docket 03N–0361).

As part of its Counterfeit Drug Initiative, FDA sought comment on the most effective ways to achieve the goals of PDMA. In particular, given recent or impending advances in technology, the agency requested comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree. Although

many comments received by the Task Force supported the use of paper pedigrees for their deterrent value and as a means to verify prior sales through due diligence, the majority of comments confirmed that significant concerns persist regarding the feasibility and limitations of full implementation of the PDMA pedigree requirements. Some comments suggested a risk-based approach to implementing PDMA, focusing on those drugs that are at high-risk of being counterfeited. For example, some comments suggested that drugs at high risk for counterfeiting maintain a full pedigree that documents all sales and transactions back to the manufacturer. One comment suggested an interim solution of "one forward, one back" pedigree for most likely to be counterfeited. The majority of comments, however, supported the eventual use of an electronic pedigree for all drug products in the supply chain and indicated that an electronic pedigree should be considered as a long-term solution to fulfilling the PDMA requirements codified at § 203.50.

In response to these comments, FDA is continuing to work closely with affected parties to identify and resolve concerns related to the implementation of the pedigree requirements of the PDMA. FDA is encouraged by the enthusiasm and interest that stakeholders in the U.S. drug supply chain have expressed toward the adoption of sophisticated track and trace technologies. Although there are technical, operational, and regulatory issues that have yet to be resolved, these are being considered and addressed by FDA and stakeholders. Currently, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. If this capability is widely adopted, a de facto electronic pedigree will follow the product from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, this electronic pedigree could meet the

statutory requirement in 21 U.S.C. 353(e)(1)(A) that "each person who is engaged in the wholesale distribution of a drug*** who is not the manufacturer or authorized distributor of record of such drug*** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)" The permanent electronic pedigree would address the concerns that have been expressed by wholesalers, particularly secondary wholesalers, regarding access to pedigrees because the required information would travel with the product at all times, regardless of whether a party to the transaction is an authorized distributor of record.

Until the electronic pedigree is in widespread use, FDA believes that the multi-layer strategies and measures discussed in the FDA's Counterfeit Drug Final Report (Final Report) can help reduce the likelihood that counterfeit drugs will be introduced into the U.S. drug distribution system. These measures, combined with implementation of Radio Frequency Identification (RFID) technology, could provide effective long-term protections to help minimize the number of counterfeit drug products in the U.S. distribution system. As discussed in greater detail in the Final Report, such long-term measures include the following: Use of authentication technologies in products and packaging and labeling, in particular, for drugs most likely to be counterfeited; adoption of secure business practices by stakeholders; adoption of the revised model rules for wholesale distributor licensure by States; stronger criminal penalties and enforcement at the State and national levels; and education and outreach to stakeholders, including greater communication through the counterfeit alert network.

Although FDA is further delaying the effective date of §§ 203.3(u) and 205.30, the agency encourages wholesalers to provide pedigree information that documents the prior history of the product, particularly for most likely to be counterfeited, even when such a pedigree is not required by the act. The suggestion from the comments that there be a one-forward, one-back pedigree for high-risk drugs until an electronic pedigree is uniformly adopted may have some merit. However, FDA believes legislative changes would be needed before it could adopt such a system.

To summarize, FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree. As stated previously, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. Therefore, to allow stakeholders to continue to move toward this goal, FDA has decided to delay the effective date of §§ 203.3(u) and 203.50 until December 1, 2006. Before the effective date, FDA intends to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of PDMA, and determine whether to further delay the effective date of the regulations or take other appropriate regulatory action.

FDA is also further delaying the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities. This further delay is necessary to give FDA additional time to address concerns about the requirements raised by affected parties and consider whether regulatory changes are appropriate and, if so, initiate such changes.

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 FDA works with industry to resolve concerns about these provisions either with the implementation of technological solutions (§§ 203.3(u) and 203.50) or the consideration of possible regulatory changes (§ 203.3(q)). 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. In addition, given the imminence of the current compliance date, seeking prior public comment on this delay is contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the compliance date for the requirements identified below, those companies affected would have to be preparing to comply with the April 1, 2004, compliance date. In accordance

with 21 CFR 10.40(c)(1), FDA is also providing an opportunity for comment on whether this delay should be modified or revoked.

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: 2-17-04
February 17, 2004

Jeffrey Shuren

Jeffrey Shuren
Assistant Commissioner for Policy

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