

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

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[Docket Nos. 1992N-0297 (formerly 92N-0297), 1988N-0258 (formerly 88N-0258), 2006D-0226]

Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; announcement of effective date; notice of availability; request for comment.

SUMMARY: The Food and Drug Administration (FDA) does not intend to further delay the effective date of certain provisions of the final regulation published in the **Federal Register** of December 3, 1999 (64 FR 67720). The provisions will therefore go into effect on December 2, 2006. In addition, FDA is announcing the availability of a new compliance policy guide (CPG) 160.900 entitled "Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203" for public comment. This CPG describes how the agency intends to prioritize its enforcement efforts during the next year with respect to pedigree requirements set forth in the Federal Food, Drug, and Cosmetic Act (the act) and certain FDA regulations.

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DATES: The effective date for §§ 203.3(u) and 203.50 is December 2, 2006. You may submit written or electronic comments on the CPG by [insert date 30 days after date of publication in the **Federal Register**].

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ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG document.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION:

I. Background

A. Implementation of §§ 203.3(u) and 203.50 of 21 CFR Part 203

The Prescription Drug Marketing Act of 1987 (the PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the act (21 U.S.C. 331, 333, 353, 381) to establish, among other things, requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

Section 503(e)(1)(A) of the act establishes the so-called "pedigree" requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the dates

of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug. The PDMA states that an authorized distributor of record is a wholesaler that has an “ongoing relationship” with a manufacturer to distribute that manufacturer’s drug. However, the PDMA does not define “ongoing relationship.”

In 1999, FDA published final regulations implementing the PDMA (part 203 (21 CFR part 203)). The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to the provisions in §§ 203.3(u) and 203.50. Section 203.3(u) defines “ongoing relationship” to include a written agreement between manufacturer and wholesaler. Section 203.50 specifies the fields of information that must be included in the drug pedigree and states that the information must be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of §§ 203.3(u) and 203.50 several times.

Most recently, in February 2004, FDA delayed the effective date of §§ 203.3(u) and 203.50 until December 1, 2006, in part because we were informed by stakeholders in the U.S. drug supply chain that the industry would voluntarily implement electronic track and trace technology by 2007. If widely adopted, this technology could create a de facto electronic pedigree documenting the sale of a drug product from its place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, an electronic record could thus meet the pedigree requirements in section

503(e)(1)(A) of the act. Based on a recent fact-finding effort by FDA to assess the use of e-pedigree across the supply chain, however, it appears that industry will not fully implement track and trace technology by 2007.

Today, the agency is announcing that it does not intend to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006. As such, these provisions defining "ongoing relationship" and setting forth requirements regarding the information that must appear in pedigrees will go into effect as of December 2, 2006.

B. CPG

We are issuing a draft CPG that describes how we plan to prioritize our enforcement actions during the next year with respect to these new requirements. To this end, FDA is announcing the availability of a new CPG Section 160.900, entitled "Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203." This CPG, which the agency is publishing in draft for comment, lists factors that FDA field personnel are expected to consider in prioritizing FDA's pedigree-related enforcement efforts during the next year. Consistent with our risk-based approach to the regulation of pharmaceuticals, these factors focus our resources on drug products that are most vulnerable to counterfeiting and diversion or that are otherwise involved in illegal activity.

FDA has not provided in the CPG a list of drug products that have been counterfeited in the past. We solicit comment on the merit of providing such a list.

The priorities described in the CPG reflect a phased-in type approach to the enforcement of the stayed pedigree provisions. The CPG will expire 1 year after the final CPG is issued. By providing guidance on the types of drugs that

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are currently of greatest concern to FDA, we believe that wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems to come into complete compliance with part 203 for all the prescription drugs they distribute.

FDA is issuing this CPG as a level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115).

We note that guidance documents are not binding on FDA or industry, and, under appropriate circumstances, the agency may initiate regulatory action, including a criminal prosecution, for pedigree violations that do not meet the factors set forth in the CPG.

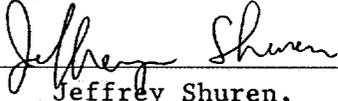
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the CPG document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this guidance is available on the Internet at <http://www.fda.gov/ora> under "Compliance Reference".

Dated: 6-7-06
June 7, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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