

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the information collection provisions by June 13, 2003.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR Part 3 (OMB Control Number 0910-0435)—Extension

The Food and Drug Administration (FDA) is requesting OMB approval under the Paperwork Reduction Act (44 U.S.C. 3507) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100-293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk of counterfeit, adulterated, misbranded, subpotent, or expired drugs being sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had

developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements:

TABLE 1.—REPORTING REQUIREMENTS

21 CFR Section	Reporting and Recordkeeping Requirements
203.11	Applications for re-importation to provide emergency medical care.
203.30(a)(1) and (b)	Drug sample requests for drug samples distributed by mail or common carrier.
203.30(a)(3), (a)(4), and (c)	Drug sample receipts for drug samples distributed by mail or common carrier.
203.31(a)(1) and (b)	Drug sample requests for drug samples distributed by means other than the mail or a common carrier.
203.31(a)(3), (a)(4), and (c)	Drug sample receipts for drug samples distributed by means other than the mail or a common carrier.
203.37(a)	Investigation of falsification of drug sample records.
203.37(b)	Investigation of a significant loss or known theft of drug samples.
203.37(c)	Notification that a representative has been convicted of certain offenses involving drug samples.
203.37(d)	Notification of the individual responsible for responding to a request for information about drug samples.
203.38(a)	Printing lot or control numbers on the drug sample unit label.
203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.
203.50(a)	Drug origin statement.
203.23(a) and (b)	Credit memorandum for returned drugs.
203.23(c)	Documentation of proper storage, handling, and shipping conditions of returned drugs.
203.30(a)(2) and 203.31(a)(2)	Verification that a practitioner requesting a drug sample is licensed or authorized to prescribe the product.
203.31(d)(4)	Investigation of apparent discrepancies and significant losses revealed through the reconciliation report.
203.31(e)	Lists of manufacturers' and distributors' representatives.
203.34	Written policies and procedures describing administrative systems.
203.37(a)	Report of investigation of falsification of drug sample records.
203.37(b)	Report of investigation of significant loss or known theft of drug samples.
203.38(b)	Records of drug sample distribution identifying lot or control numbers of samples distributed.
203.39(d)	Records of drug samples destroyed or returned by a charitable institution.