complete a brief quantitative interview after HIV referral or HIV testing is offered to them. HIV-seropositive injection-drug-using syringe customers who are identified during HIV testing will be immediately linked to social and medical services. Ten of the 12 ESAP Pharmacies will provide referrals to local HIV testing sites for their injection-drug-using syringe customers. At these ten pharmacies, 40 adult pharmacy staff will be surveyed on pharmacy staff attitudes and behaviors regarding HIV testing and referral.

The remaining two ESAP pharmacies will pilot test the feasibility of offering and performing HIV counseling and testing in the pharmacy for injection-drug-using syringe customers. At these two pharmacies, 8 adult (age ≥18 yrs) pharmacy staff members will be surveyed on pharmacy staff attitudes and behaviors regarding HIV testing and referral. At the 12 pharmacies, 12 pharmacy staff members (one from each pharmacy) will be surveyed monthly to track study progress and obstacles to completing the study. Twelve pharmacy staff members (one from each pharmacy) will complete a daily syringe sales and referral log.

There is no cost to the injection drug using customers who provide information to this study other than their time. The total estimated annual burden hours are 496 hours.

ESTIMATE OF ANNUALIZED BURDEN TABLE

| Respondent | Form name | No. of respondents | No. of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|---|
| Pharmacist | Pharmacy telephone screening and enrollment form. | 8 | 1 | 10/60 |
| Pharmacist and Pharmacy Technician | Pharmacy staff baseline survey | 48 | 1 | 20/60 |
| Pharmacist and Pharmacy Technician | Pharmacy staff six monthly survey | 48 | 2 | 20/60 |
| Pharmacist and Pharmacy Technician | Pharmacy staff exit survey | 48 | 1 | 20/60 |
| Pharmacist | Pharmacy staff monthly survey | 12 | 10 | 10/60 |
| Pharmacy Technician | Syringe sales and referral log | 12 | 300 | 5/60 |
| Syringe-customer study participant | Pharmlink Participant Baseline Survey | 221 | 1 | 30/60 |

Dated: August 26, 2009.

**Marilyn S. Radke,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E9–21037 Filed 8–31–09; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0131]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing Act of 1987

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information 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 collection of information by October 1, 2009.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792, Elizabeth.Berbakos@fda.hhs.gov.

**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; 21 CFR Part 203 (OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501–3520) 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 that counterfeit, adulterated, misbranded, subpotent, or expired drugs are 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 203.11 | Applications for reimportation to provide emergency medical care. |
| 21 CFR 203.30(a)(1) and (b) | Drug sample requests (drug samples distributed by mail or common carrier). |
| 21 CFR 203.30(a)(3), (a)(4), and (c) | Drug sample receipts (receipts for drug samples distributed by mail or common carrier). |
| 21 CFR 203.31(a)(1) and (b) | Drug sample requests (drug samples distributed by means other than the mail or a common carrier). |
| 21 CFR 203.31(a)(3), (a)(4), and (c) | Drug sample receipts (drug samples distributed by means other than the mail or a common carrier). |
| 21 CFR 203.37(a) | Investigation of falsification of drug sample records. |
| 21 CFR 203.37(b) | Investigation of a significant loss or known theft of drug samples. |
| 21 CFR 203.37(c) | Notification that a representative has been convicted of certain offenses involving drug samples. |
| 21 CFR 203.37(d) | Notification of the individual responsible for responding to a request for information about drug samples. |
| 21 CFR 203.39(g) | Preparation by a charitable institution of a reconciliation report for donated drug samples. |

TABLE 2.—RECORDKEEPING REQUIREMENTS

| | |
|---|---|
| 21 CFR 203.23(a) and (b) | Credit memo for returned drugs. |
| 21 CFR 203.23(c) | Documentation of proper storage, handling, and shipping conditions for returned drugs. |
| 21 CFR 203.30(a)(2) and 21 CFR 203.31(a)(2) | Verification that a practitioner requesting a drug sample is licensed or authorized by the appropriate State authority to prescribe the product. |
| 21 CFR 203.31(d)(1) and (d)(2) | Contents of the inventory record and reconciliation report required for drug samples distributed by representatives. |
| 21 CFR 203.31(d)(4) | Investigation of apparent discrepancies and significant losses revealed through the reconciliation report. |
| 21 CFR 203.31(e) | Lists of manufacturers' and distributors' representatives. |
| 21 CFR 203.34 | Written policies and procedures describing administrative systems. |
| 21 CFR 203.37(a) | Report of investigation of falsification of drug sample records. |
| 21 CFR 203.37(b) | Report of investigation of significant loss or known theft of drug samples. |
| 21 CFR 203.38(b) | Records of drug sample distribution identifying lot or control numbers of samples distributed. (The information collection in 21 CFR 203.38(b) is already approved under OMB control number 0910–0139). |
| 21 CFR 203.39(d) | Records of drug samples destroyed or returned by a charitable institution. |
| 21 CFR 203.39(e) | Record of drug samples donated to a charitable institution. |
| 21 CFR 203.39(f) | Records of donation and distribution or other disposition of donated drug samples. |
| 21 CFR 203.39(g) | Inventory and reconciliation of drug samples donated to charitable institutions. |
| 21 CFR 203.50(a) | Drug origin statement. |
| 21 CFR 203.50(b) | Retention of drug origin statement for 3 years. |
| 21 CFR 203.50(d) | List of authorized distributors of record. |

The reporting and recordkeeping requirements are intended to help achieve the following goals:

(1) To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care;

(2) To ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample;

(3) To limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other health care entities at the request of a licensed or authorized practitioner;

(4) To require licensed or authorized practitioners to request prescription drug samples in writing;

(5) To mandate storage, handling, and recordkeeping requirements for prescription drug samples;

(6) To prohibit, with certain exceptions, the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or other health care entities, or which were donated or supplied at a reduced price to a charitable organization;

(7) To require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

In the **Federal Register** of March 24, 2009 (74 FR 12365), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment.

*Comment Summary*: The comment pertained to the recordkeeping requirements in § 203.50(a) and (b) (21 CFR 203.50(a) and (b)).

The comment concluded that FDA's estimate of ''0'' recordkeeping hours for these regulations in table 2 of the March 24, 2009, notice was in error. In summary, the comment contended: (1) Pedigrees must be passed by nonauthorized distributors of record prior to each wholesale distribution; (2) all wholesale distributors that provide or receive pedigrees after December 1, 2006, must retain copies of the pedigrees for 3 years; and (3) those records must include names and addresses of all parties to the transaction and the date of the transactions.

The comment offered no estimates for the recordkeeping provisions in § 203.50(a) and (b). The comment explained that it is unable to suggest estimates for the burden hours because most of its members ''have likely received a designation of 'ADR' status by most drug manufacturers for most of the prescription drug products that they purchase, and they provide pedigrees only on a limited basis.'' Thus, the comment said, there are a large number of distributors that are not members of its organization but are subject to the pedigree requirements and, therefore, the burden hours that its members alone accrue would not be reflective of the entire population of distributors that are affected, and would likely be a minority of the total burden hours that all distributors experience.

The comment recommended that FDA ''conduct a PRA review and estimate of the paperwork burden for healthcare distributors to comply with these regulations.''

*FDA Response*: FDA appreciates the comment and, as requested, we plan to conduct research to obtain estimates for the burden hours that may be currently incurred by distributors to comply with the recordkeeping provisions in § 203.50. We are requesting that interested persons submit to the docket (identified in brackets in the heading of this document) data on the burden hours currently incurred by distributors to comply with the recordkeeping provisions in § 203.50. In response to the comment, we are also adding to the Estimated Annual Recordkeeping Burden (table 4 of this document) recordkeeping estimates for § 203.50. We used these estimates in previous **Federal Register** notices based on information we received at that time, and no comments were received on these burden hours. If our research results in new data that differs from these estimates, we will amend the approval for OMB control number 0910–0435 to include revised estimates for these provisions.

FDA estimates the burden of this collection of information as follows:

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours[2] |
|---|---|---|---|---|---|
| 203.11 | 1 | 1 | 1 | .5 | 1 |
| 203.30(a)(1) and (b) | 61,961 | 12 | 743,532 | .06 | 44,612 |
| 203.30(a)(3), (a)(4), and (c) | 61,961 | 12 | 743,532 | .06 | 44,612 |
| 203.31(a)(1) and (b) | 232,355 | 135 | 31,367,925 | .04 | 1,254,717 |
| 203.31(a)(3), (a)(4), and (c) | 232,355 | 135 | 31,367,925 | .03 | 941,038 |
| 203.37(a) | 50 | 4 | 200 | .25 | 50 |
| 203.37(b) | 50 | 40 | 2,000 | .25 | 500 |
| 203.37(c) | 1 | 1 | 1 | 1 | 1 |
| 203.37(d) | 50 | 1 | 50 | .08 | 4 |
| 203.39(g) | 1 | 1 | 1 | 1 | 1 |
| Total Reporting Burden Hours | | | | | 2,285,536 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates are not exact due to rounding.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Recordkeeping | Total Annual Responses | Hours per Response | Total Hours[2] |
|---|---|---|---|---|---|
| 203.23(a) and (b) | 31,676 | 5 | 158,380 | .25 | 39,595 |
| 203.23(c) | 31,676 | 5 | 158,380 | .08 | 12,670 |

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

| 21 CFR Section | No. of Respondents | Annual Frequency per Recordkeeping | Total Annual Responses | Hours per Response | Total Hours[2] |
|---|---|---|---|---|---|
| 203.30(a)(2) and 203.31(a)(2) | 2,208 | 100 | 220,800 | .50 | 110,400 |
| 203.31(d)(1) and (d)(2) | 2,208 | 1 | 2,208 | 40 | 88,320 |
| 203.31(d)(4) | 442 | 1 | 442 | 24 | 10,608 |
| 203.31(e) | 2,208 | 1 | 2,208 | 1 | 2,208 |
| 203.34 | 90 | 1 | 90 | 40 | 3,600 |
| 203.37(a) | 50 | 4 | 200 | 6 | 1,200 |
| 203.37(b) | 50 | 40 | 2,000 | 6 | 12,000 |
| 203.39(d) | 65 | 1 | 65 | 1 | 65 |
| 203.39(e) | 3,221 | 1 | 3,221 | .50 | 1,610 |
| 203.39(f) | 3,221 | 1 | 3,221 | 8 | 25,768 |
| 203.39(g) | 3,221 | 1 | 3,221 | 8 | 25,768 |
| 203.50(a) | 125 | 100 | 12,500 | .17 | 2,125 |
| 203.50(b) | 125 | 100 | 12,500 | .50 | 6,250 |
| 203.50(d) | 691 | 1 | 691 | 2.0 | 1,382 |
| Total Recordkeeping Burden Hours | | | | | 332,769 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates are not exact due to rounding.

Dated: August 25, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–21026 Filed 8–31–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0406]**

### Agency Emergency Processing Under Office of Management and Budget Review; Tobacco Product Establishment Registration and Submission of Certain Health Information

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the submission of tobacco product establishment registration and submission of certain health information, including ingredient listing and health related documents, as required by The Family Smoking Prevention and Tobacco Control Act (FSPTCA).

**DATES:** Fax written comments on the collection of information by September 16, 2009. FDA is requesting approval of this emergency processing by September 16, 2009.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974. All comments should be identified with the title, ''Tobacco Product Establishment Registration and Submission of Certain Health Information.'' Also include the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, e-mail: *Jonnalynn.Capezzuto@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. On June 22, 2009, the President signed FSPTCA into law (Public Law 111–31). Section 101 of FSPTCA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding, among other things, new sections 904 (21 U.S.C. 394) and 905 (21 U.S.C. 395). Section 905 requires the annual registration of any ''establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.'' Section 905 also requires this registration be completed by December 31 of each year. To allow adequate time for establishment owners and operators to complete the registration process, and to match similar provisions applicable to other FDA regulated products, FDA plans to begin accepting establishment registrations on October 1, 2009.

Section 904(a)(1) of the act requires each tobacco product manufacturer or importer, or agent thereof to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. Section 904(a)(4) requires each tobacco