Regulations in 42 CFR, Sections 413.337, 413.343, 424.32, and 483.20; *Form No.:* CMS–R–250 (OMB# 0938–0739); *Use:* Skilled Nursing Facilities (SNFs) are required to submit the resident assessment data as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337. Pursuant to sections 4204(b) and 4214(d) of OBRA 1987, the current requirements related to the submission and retention of resident assessment data for the 5th, 30th, 60th, and 90th days following admission, necessary to administer the payment rate methodology described in Section 413.337, are subject to the Paperwork Reduction Act. The burden associated with this is the SNF staff time required to complete the Minimum Data Set (MDS), SNF staff time to encode, and SNF staff time spent in transmitting the data.; *Frequency:* Monthly; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 17,000; *Total Annual Responses:* 2,657,859; *Total Annual Hours:* 1,993,394.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 21, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02–30365 Filed 11–29–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0486]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100–293).

DATES: Submit written or electronic comments on the collection of information by January 31, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

FDA is requesting OMB approval under the PRA for the reporting and recordkeeping requirements contained in the regulations implementing PDMA. 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 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 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 American goods returned causing a health and safety risk to American 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 American 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 AND RECORDKEEPING REQUIREMENTS

21 CFR Section	Requirements
203.11	Applications for reimportation to provide emergency medical care.
203.30(a)(1) and (b)	Drug sample requests (drug samples distributed by mail or common carrier).
203.30(a)(3), (a)(4), and (c)	Drug sample receipts (receipts for drug samples distributed by mail or common carrier).
203.31(a)(1) and (b)	Drug sample requests (drug samples distributed by means other than the mail or a common carrier).
203.31(a)(3), (a)(4), and (c)	Drug sample receipts (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 memo for returned drugs.
203.23(c)	Documentation of proper storage, handling, and shipping conditions for 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)(1) and (d)(2)	Contents of the inventory record and reconciliation report required for drug samples distributed by representatives.
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.
203.39(e)	Record of drug samples donated to a charitable institution.
203.39(f)	Records of donation and distribution or other disposition of donated drug samples.
203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
203.50(a)	Drug origin statement.
203.50(b)	Retention of drug origin statement for 3 years.
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 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 samples in writing;

(5) To mandate storage, handling, and recordkeeping requirements for 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.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.11	12	1	12	.5	6
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)	25	1	25	6.00	150
203.37(b)	200	1	200	6.00	1,200
203.37(c)	50	1	50	1.00	50

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.37(d)	2,208	1	2,208	.08	177
203.38(a)	2,208	1	2,208	3.00	6,624
203.39(g)	3,221	1	3,221	2.00	6,442
203.50(a)	125	100	12,500	.08	1,000
Total					2,300,628

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
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	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.38(b)	2,208	14,543	32,111,457	.02	642,229
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768
203.39(g)	3,221	1	3,221	8.00	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	2.00	1,382
Total					1,061,368

[1] There are no operating and maintenance costs or capital costs associated with this collection of information.

Dated: November 21, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30404 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1527]

Laverne M. Charpentier; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Ms. Laverne M. Charpentier's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Ms. Laverne M. Charpentier for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Charpentier was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a Government agency, and that Ms. Charpentier's conduct undermined the process for the regulation of drugs. Ms. Charpentier has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective December 2, 2002.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On October 21, 1997, the U.S. District Court for the Central District of California accepted the plea of Ms. Laverne M. Charpentier to one count of conspiring to make false statements in matters within the jurisdiction of a Government agency under 18 U.S.C. 371 and 1001.

Ms. Charpentier, a former drug study coordinator, was employed by a private company retained by drug manufacturers to conduct clinical studies of new pharmaceutical products to be submitted to FDA in support of approval of the drug products. In her capacity as a drug study coordinator, Ms. Charpentier participated in the conduct of clinical studies to test the safety and effectiveness of investigational new drugs. Ms. Charpentier admitted that she, among other things: (1) Falsely reported that certain subjects participated in clinical trials when in fact, they had not; (2) substituted samples and data from qualifying subjects for nonqualifying subjects; and (3) enrolled nonexistent and nonqualifying subjects in the clinical studies and falsified data for those nonexistent and nonqualifying subjects.

As a result of Ms. Charpentier's conviction, FDA served her by certified letter on May 14, 2002, a proposal to debar her for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Ms. Charpentier an opportunity for a hearing on the proposal. FDA based the debarment proposal on a