Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' available at *http://www.cfsan.fda.gov/~dms/prodguid.html*. The guidance addresses microbial food safety hazards and good agricultural and good management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form.

There is evidence that growers have not fully implemented the GAPs to reduce production risks, despite intensive GAPS training programs. FDA is planning to conduct a study to determine growers' decision-making processes with regard to understanding and implementing GAPs on the farm, to more fully understand the barriers and constraints associated with GAPs implementation.

The project will use ''mental modeling,'' a qualitative research method wherein the decision-making processes of a group of respondents (described below) concerning the implementation of GAPs on the farm are modeled and compared to a model based on expert knowledge and experience in the implementation of GAPs. The information will be collected via a telephone interview concerning the factors that influence the perceptions and motivations related to the implementation of GAPs. A comparison between expert and consumer models based on the collected information may identify ''consequential knowledge gaps'' that can be redressed through information campaigns designed by FDA.

Description of respondents:

Respondents will be farmers or growers, GAPs trainers, and retail buyer and/or grower association representatives.

In the **Federal Register** of July 1, 2008 (73 FR 37464), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received one letter in response to the notice, containing one or more comments. One comment recommended that FDA increase the sample size and ensure that key subsets of the produce industry are surveyed. FDA responds that the proposed study is qualitative in nature. FDA does not intend the results of this study to be a quantitative estimate of the prevalence of the use of GAPs across the produce industry. The proposed sample size is sufficient to enable FDA to construct mental models of the barriers and constraints related to GAPs implementation. FDA agrees with the recommendation to ensure key subsets of the industry are included in the study.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	80	1	80	0.02	2
Pre-tests/ Cognitive Interviews	9	1	9	.75	6.75
Farmers/ Growers	24	1	24	.75	18
GAPs Trainers	24	1	24	.75	18
Retail Buyers/ Growers Association Representatives	12	1	12	.75	9
Total					53.75

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

In the 60-day notice published on July 1, 2008, FDA estimated the total burden hours to be 51.75. FDA has made changes to its burden estimate, reflected in table 1 of this document. FDA added a screener and listed the participants separately in the table. The new total burden hours are estimated to be 53.75 and are described in the following paragraphs.

Approximately 80 respondents will be screened. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions, for a total of 1.6 hours (rounded to 2). FDA will conduct 9 pretests; we estimate that it will take respondents 45 minutes (0.75 hours) to complete the pretest, for a total of 6.75 hours. Sixty respondents will complete the interview. We estimate that it will take respondents 45 minutes (0.75 hours) to complete the entire interview, for a total of 45 hours. Thus, the total estimated burden is 53.75 hours. FDA's burden estimate is based on prior experience with mental models research that is similar to this proposed study.

The study will involve approximately 60 respondents, including 24 farmers or growers of fruits and vegetables, 24 GAPs trainers, and 12 retail buyer or grower association representatives. FDA estimates that each respondent will take 45 minutes (0.75 hours) to complete the interview for the study (60 respondents x 0.75 hours = 45 hours).

Thus, the total annual burden for this one-time collection of information is 53.75 hours (2 hours + 6.75 hours + 45 hours = 53.75 hours). These estimates are based on FDA's experience with consumer research.

Dated: March 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6393 Filed 3–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

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 May 26, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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 these topics: (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 203 (OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the Paperwork Reduction Act (44 USC 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the PDMA. 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:

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.

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 U.S., 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
203.11	1	1	1	.5	0.5
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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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					2,285,535.50

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	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	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)	0	0	0	0	0
203.50(b)	0	0	0	0	0
203.50(d)	0	0	0	0	0
Total					324,092

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

Dated: March 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6394 Filed 3–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. Vaccine Design PO1.

Date: April 16, 2009.