

assesses the effectiveness of CMS' quality reporting activities.

- Effectively communicates program policies related to the Prescription Drug and Medicare Advantage (MA) programs to health plans and drug plan contractors, employer group sponsors, beneficiary advocates and other stakeholders in the health care field.

- Develops new policies (e.g. health plan access, benefits, special needs plans) and programs to reflect changes in program objectives, the health care delivery system, beneficiary health care needs, and new plan types to support an appropriate range of choices for beneficiaries.

- Collaborates with our partners, such as industry, other government entities and advocacy groups, to understand their perspectives on Prescription Drug and Medicare Managed Care policies and procedures and to drive best practices in the health care industry.

- Develops and implements a comprehensive strategic plan, objectives and measures for overseeing an effective compliance and oversight program for all Part C (Medicare Advantage) and Part D (Medicare Prescription Drug) contractors in close collaboration with CMHPO, the Medicare Drug Benefit and C & D Data Group, the Medicare Drug and Health Plan Contract Administration Group and other Center for Drug and Health Plan Choice components.

- Develops and implements a comprehensive and effective audit program for all Part C (Medicare Advantage) and Part D (Medicare Prescription Drug) contractors.

Dated: June 21, 2008.

James W. Weber,

Acting Director, Office of Operations Management, Centers for Medicare & Medicaid Services.

[FR Doc. E8-14896 Filed 6-30-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0188] (formerly Docket No. 2004N-0081)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Request for Designation as Country not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured from, Processed With, or Otherwise Containing, Material from Cattle" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 17, 2008 (73 FR 20785), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0623. The approval expires on June 30, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-14882 Filed 6-30-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0354]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Farmers' Understanding and Implementation of Good Agricultural Practices

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed study entitled "Mental Models Study of Farmers' Understanding and Implementation of Good Agricultural Practices."

DATES: Submit written or electronic comments on the collection of information by September 2, 2008.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (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:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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 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.

Mental Models Study of Farmers' Understanding and Implementation of Good Agricultural Practices

The proposed information collection will help FDA protect the public from foodborne illness by increasing the agency's understanding of how farmers

and growers use Good Agricultural Practices (GAPs) to address common risk factors in their operations and thereby minimize food safety hazards potentially associated with fresh produce. Fresh fruits and vegetables are those that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form and that are reasonably likely to be consumed raw. Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393 (b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. Under Title 42 of the Public Health Service Act (1944), FDA has authority to act to protect the public health.

In 1998, FDA issued a guidance document entitled "Guide to Minimize 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pre-tests/ Cognitive Interviews	9	1	9	.75	6.75
Study	60	1	60	.75	45
Total					51.75

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

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 will also conduct a pretest using 9 respondents. 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 51.75 hours (6.75 hours + 45 hours = 51.75 hours). These estimates are based on FDA's experience with consumer research.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to

the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0146]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing