

pharmaceutical therapy and that there are morbidity and mortality consequences. The Administration has developed a proposal for paying for prescriptions for low-income elderly Medicaid recipients. This proposal will allow States to run 1115 demonstration projects specifically for a drug benefit for the elderly.

CMS has recently completed work on an innovative, electronic approach for easing the burden of States in applying for participation in the Pharmacy Plus demonstration initiative. We are seeking approval of the forms that would be used to collect data from applicants under this initiative.

The initiative will greatly reduce the time period required for States to develop and apply for demonstration authority; in addition the initiative is intended to expedite the review and approval time required by CMS. The initiative specifies the requirements of States to participate in the initiative—if the criteria are met by the State then deliberation by CMS on the application should be minimal. The result will be an expeditious approval, implementation and operation of demonstration programs that will provide prescription coverage to lessen the morbidity and mortality that is occurring. Without approval of these forms on an emergency basis, millions of Seniors will continue to under-utilize pharmaceutical therapy for chronic and acute morbidity. The use of the forms will expedite prescription coverage and utilization of important medicines.

CMS is requesting OMB review and approval of this collection by January 28, 2003, with a 180-day approval period. Written comments and recommendation will be accepted from the public if received by the individuals designated below by January 27, 2003.

Type of Information Collection Request: New collection; *Title of Information Collection:* Pharmacy Plus Template for Low Income Seniors under Medicaid; Form No.: CMS-10067 (OMB# 0938-XXXX); *Use:* The template for the Pharmacy Plus program for low income seniors under Medicaid will enable states to apply, via a standard format, to provide a drug benefit to elderly recipients; use of this format will expedite the process of obtaining CMS review and approval of an application; *Frequency:* Other: 3 years after initial submission for the 1915 (c) waiver; 5 years after initial submission for the 1115 demonstration; *Affected Public:* State Government; *Number of Respondents:* 51; *Total Annual Responses:* 25; *Total Annual Hours:* 115.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

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://www.hcfa.gov/regs/prdact95.htm>, 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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by January 27, 2003:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850. Fax Number: (410) 786-0262. Attn: Julie Brown, CMS-10067. And, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. Attn.: Brenda Aguilar, CMS Desk Officer.

Dated: January 8, 2003.

Julie Brown,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0131]

Agency Information Collection Activities; Announcement of OMB Approval; FDA Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing that a proposed collection of information entitled "FDA Rapid Response Surveys"

has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 16, 2002 (67 FR 63928), 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 0910-0500. The approval expires on June 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 9, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0284]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling: Health Claims; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling: Health Claims; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.