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.

[FR Doc. 03–910 Filed 1–15–03; 8:45 am]

BILLING CODE 4120–03–P

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.

[FR Doc. 03–903 Filed 1–15–03; 8:45 am]

BILLING CODE 4160–01–S

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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 16, 2002 (67 FR 63931), 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 0910–0428. The approval expires on December 31, 2005. 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.

[FR Doc. 03–905 Filed 1–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1528]

Delfina Hernandez; Rescission of Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is rescinding an order issued under the Federal Food, Drug, and Cosmetic Act (the act) debarring Ms. Delfina Hernandez for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA is issuing this rescission because service of a notice proposing to debar Ms. Hernandez and offering her an opportunity for a hearing on the proposal was sent to the wrong person.

DATES: This notice is effective November 6, 2002.

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: In the **Federal Register** of November 6, 2002 (67 FR 67629), FDA issued an order debarring Ms. Delfina Hernandez for 5 years from providing services in any capacity to a person that has an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))).

The debarment order stated that FDA had served Ms. Hernandez by certified mail on May 13, 2002, a notice proposing to debar her and offering her an opportunity for a hearing on the proposal. The debarment order further stated that Ms. Hernandez had failed to request a hearing and thereby waived her opportunity for a hearing and waived any contentions concerning her debarment.

FDA has learned that the notice proposing to debar Ms. Hernandez and offering her an opportunity for a hearing was sent to an incorrect address and was apparently signed for by a person with the same name as Ms. Hernandez, but who was not the intended subject of the notice. Accordingly, FDA is rescinding the November 6, 2002, order.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.34).

Dated: January 2, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–1020 Filed 1–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0361]

International Conference on Harmonisation; Guidance on Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance is an annex to an ICH guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products'' (66 FR 56332, November 7, 2001). It is intended to provide guidance on the application of reduced designs (i.e., bracketing and matrixing) for stability studies conducted in accordance with the principles outlined in ICH Q1A(R).

DATES: The guidance is effective January 16, 2003. Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Chi-wan Chen, Center for Drug Evaluation and Research (HFD–830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2001, or Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–402–4635.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance