42 CFR	OMB Control Nos.
489.66, 489.67	0938–0713
489.102	0938–0610
491.1–.11	0938–0074
491.3, 491.8	0938–0792
491.9	0938–0334
491.11	0938–0792
493.1–.2001	0938–0151, 0544, 0581, 0599, 0612, 0650 & 0653
493.551–.557	0938–0686
493.1269–.1285	0938–0170
493.1840	0938–0655
498.40–.95.	0938–0486 & 0567
1003.100, 1003.101, 1003.103.	0938–0700
1004.40, 1004.50, 1004.60, 1004.70.	0938–0444

45 CFR	OMB. Control Nos
5b	0938–0734
146	0938–0702
146.121	0938–0819
146.141	0938–0827
148	0938–0703 & 0797
162	0938–0866

Dated: August 20, 2002.

John P. Burke, III,

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

[FR Doc. 02–21711 Filed 8–26–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0007]

Agency Information Collection Activities; Announcement of OMB Approval; CGMP Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''CGMP Regulations for Finished Pharmaceuticals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 2002 (67 FR 34939), 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 0910–0139. This approval expires on August 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: August 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–21735 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications (Catalog of Federal Domestic Assistance No. 93.103)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal year (FY) 2003. This announcement supercedes the previous announcement of this program, which was published in the **Federal Register** on August 27, 2001.

DATES: The application receipt dates are October 16, 2002, and April 2, 2003.

ADDRESSES: Application requests and completed applications should be submitted to Maura Stephanos, Grants Management Specialist, Grants Management Staff, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183, FAX 301–827–7101, e-mail: mstepha1@oc.fda.gov. Applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857. Applications may also be obtained from the OPD on the Internet at http://www.fda.gov/orphan or at http://grants.nih.gov/grants/funding/phs398/phs398.html. Note: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management issues of this notice: Maura Stephanos (see **ADDRESSES**).

Regarding the programmatic issues of this notice: Debra Y. Lewis, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 15A–08, Rockville, MD 20857, 301–827–3666, FAX 301–827–0017, e-mail: dlewis@oc.fda.gov.

SUPPLEMENTARY INFORMATION: All studies of new drug and biological products must be conducted under the FDA's investigational new drug (IND) procedures and studies of medical devices must be conducted under the investigational device exemption (IDE) procedures. Studies of approved products to evaluate new orphan indications are acceptable; however, these must also be conducted under an IND or IDE to support a change in labeling. The study protocol proposed in the grant application must be under an active IND or IDE (not on clinical hold) to qualify the application for scientific and technical review. (See Program Review Criteria for important information about the IND/IDE status of products to be studied under these grants.)

Except for medical foods that do not need premarket approval, FDA will only consider awarding grants to support premarket clinical studies to find out whether the products are safe and effective for approval under section 301 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*) or under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act. FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.