AR–12 Lobbying Restrictions

AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317(k)(2)of the Public Health Service Act, (42 U.S.C. 241(a) and 247b(k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.943.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—*http://www.cdc.gov.* Click ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Ann Cole, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement #01138, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd., Room 3000, Mailstop E–15, Atlanta, GA 30341, Telephone: (770) 488–2731, Email address: *zlr5@cdc.gov*.

For program technical assistance, contact: Jeff Efird, MPA, Deputy Chief, Epidemiology Branch, Division of HIV/AIDS Prevention Surveillance & Epidemiology, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–45, Atlanta, Georgia 30333, Telephone: (404) 639–6130, Email address: *jle1@cdc.gov*.

Dated: July 12, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–17912 Filed 7–17–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–215]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Note: For this submission, CMS is requesting public comments on the information requirements in the Final Rule published October 11, 2000 for ''Additional DMEPOS Supplier Standards'' only. CMS made an error in the last PRA submission whereas the ''Surety Bond'' requirements were referenced. Please be advised that all Surety Bond requirements have been removed and are not to be commented on at this time.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Referenced in 42 CFR 424.57: Additional DMEPOS Supplier Standards; *Form No.:* CMS–R–215 (OMB# 0938–0717); *Use:* The respondents for these information collection requirements are suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). CMS requires, upon request, documentation that the DMEPOS supplier has both advised beneficiaries that they may either rent or purchase inexpensive or routinely purchased equipment and discussed the purchase option for capped rental equipment. This criteria is necessary to determine if the supplier has met the supplier standards; *Frequency:* Annually, On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 65,400; *Total Annual Responses:* 35,000; *Total Annual Hours:* 280,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's 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. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willinghan, CMS–R–215, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 10, 2001.

Julie Brown,

Acting, CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–17877 Filed 7–17–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1674]

Agency Information Collection Activities; Announcement of OMB Approval; Specific Requirements on Content and Format of Labeling; Geriatric Use Subsection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Specific Requirements on Content and Format of Labeling; Geriatric Use Subsection'' 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 January 5, 2001 (66 FR 1142), 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 0910–0370. The approval expires on July 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov.ohrms/dockets.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17975 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1503]

Agency Information Collection Activities; Announcement of OMB Approval; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 1, 2001 (66 FR 21769), 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 0910–0167. The approval expires on July 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17978 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0178]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Premarket Notification 510(k) Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by August 17, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notification 510(k) Submissions (21 CFR Part 807) (OMB Control No. 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. The definition of ''person'' has been expanded to include hospitals who reuse or remanufacture single-use medical devices. The estimated submissions below include those submitted by hospitals remanufacturing single-use medical devices.

Section 510(k) of the act allows for exemptions to the 510(k) submissions (i.e., a premarket notification submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process). Under 21 CFR 807.85, ''Exemption from premarket notification,'' a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling and advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device, and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject's rights. The respondents to this information