AR–12—Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 20 (a) and 22(e)(7) of the Occupational Safety and Health Act of 1970 [29 U.S.C. 669(a) and 671(e)(7)]. The Catalog of Federal Domestic Assistance number is 93.262 for the National Institute for Occupational Safety and Health.

J. Where to Obtain Additional Information

Please refer to CDC Announcement Number 99037 when requesting information and submitting an application.

To receive additional written information call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name, address, and phone number and will need to refer to NIOSH Announcement 99037. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

See also the CDC home page on the Internet: *http://www.cdc.gov*.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained by contacting: Sheryl L. Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99037, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E–13, Atlanta, Georgia 30341, Email address: slh3@cdc.gov.

Program technical assistance may be obtained by contacting: Kenneth Mead, P.E., telephone (513) 841–4319, Email kcm3@cdc.gov, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Division of Physical Sciences and Engineering, 4676 Columbia Parkway, Mailstop R–5, Cincinnati, OH 45226.

National Occupational Research Agenda (NORA): CDC, NIOSH is committed to the program priorities developed by NORA. Copies of the publication, ''The National Occupational Research Agenda'' may be obtained from The National Institute of Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226–1998 or telephone 1–800–356–4674, and is available through the NIOSH Home Page, ''http://www.cdc.gov/niosh/nora.html''.

Dated: February 23, 1999.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–5034 Filed 3–1–99; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Epidemiologic Perspective on Early Hearing Detection and Intervention (EHDI).

Time and Date: 2 p.m.–3:30 p.m., (EST), March 5, 1999.

Location: Dr. Nigel Paneth, Department of Epidemiology at Michigan State University, will make a presentation at Michigan State University, East Lansing, Michigan.

Supplementary Location Information: Teleconference Access: Participants must call to be connected to the meeting. The telephone bridge number for non-Federal participants is 1/800/713–1971. The telephone bridge number for Federal participants is 404/639–4100. The conference code is: 351926. For security and confidentiality purposes, participants will not be connected to a conference call without a valid conference code. The conference name is ''Epidemiology''. For problems during the teleconference, press *0 at anytime to signal the attendant. For questions concerning technical aspects of the teleconference, please call 404/639–7550. Please note, the presentation will include visual aids that may not be readily understood by telephone participants.

Videoconference Access: Invited participants may access the meeting through Envision, at the following sites:

(1) Centers for Disease Control and Prevention, Atlanta, Georgia.

(2) Department of Education, Hubert H. Humphrey Building, Washington, DC.

(3) University of North Carolina, Research Triangle Park, North Carolina.

(4) University of Colorado, Ft. Collins, Colorado.

(5) National Institute of Child Health and Human Development, Research Triangle Park, North Carolina.

(6) Columbia University, New York, New York.

Status: This meeting is targeted for and will be presented at the graduate level of epidemiology. It may not be readily understood by the lay public. Due to limited time, questions will not be accepted from teleconference participants.

Purpose: Dr. Nigel Paneth, Department of Epidemiology at Michigan State University, will provide an overview of the epidemiology of newborn hearing screening. The presentation will be followed by a brief question and answer period.

Contact Person for More Information: Mike Adams, M.D., Division of Child Development, Disability, and Health (proposed), NCEH, CDC, 4770 Buford Highway, NE, M/S F–34, Atlanta, Georgia 30341. Telephone 770/488–7154, fax 770/488–7356.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 24, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–5086 Filed 3–1–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–484R]

Agency Information Collection Activities; Announcement of OMB Approval; Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products'' 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 14, 1998 (63 FR 26744), 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 0910–0372. The approval expires on July 31, 2001. A

copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: February 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5030 Filed 3–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0839]

Determination of Regulatory Review Period for Purposes of Patent Extension; Atacand

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Atacand and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Atacand (candesartan cilexetil). Atacand is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Atacand (U.S. Patent No. 5,196,444) from Takeda Chemical Industries Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Atacand represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Atacand is 1,087 days. Of this time, 686 days occurred during the testing phase of the regulatory review period, while 401 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 15, 1995. The applicant claims May 16, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 15, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* April 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Atacand (NDA 20,838) was initially submitted on April 30, 1997.

3. *The date the application was approved:* June 4, 1998. FDA has verified the applicant's claim that NDA 20,838 was approved on June 4, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 413 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 30, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the ¶docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–5032 Filed 3–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–228]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the