based on the rationale, intended target audience, intended outcomes for participants, and proposed evaluation plans.

2. Provide information by documenting the response to phone calls, email requests, and other referred questions generated by the dissemination of web-based materials.

3. Develop partnerships with at least 30 diverse and active national organizations representing health care practitioners that will disseminate the web-based modules to their membership: Documentation should include communications methods developed or expanded to facilitate information exchange, demonstration of feedback from the national organizations, dissemination of materials, and signed documents of collaboration.

Program Area 4: Arthritis

1. Document and report the number of training programs offered and the number of people trained in Arthritis Foundation evidence-based programs (i.e., ASHC, PACE, AF Aquatics).

2. Develop no more than five innovative self management education or physical activity programs by providing detailed descriptions of the process and outcome of program development, including scientific rationale for the program, steps taken to develop program based on the rationale, intended target audience, intended outcomes for program participants, theoretical model or framework, results of pilot testing, and proposed evaluation plans.

3. Increase capacity to provide information by documenting an increased ability to handle phone and web requests and the development and production of new materials.

The following additional requirements are applicable to these programs. For a complete description of each, see Attachment II of the announcement.

AR–7 Executive Order 12372 Review
AR–8 Public Health System Reporting requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the 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 93.283.

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 on ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from: Michelle Copeland, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 02091, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2686, E-mail: *stc8@cdc.gov.*

See also the CDC home page on the Internet to obtain a copy of the announcement: *http://www.cdc.gov.*

For program technical assistance, contact: Mike Waller, Centers for Disease Control and Prevention, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway NE, Atlanta, GA, 30341–3717, Telephone: (770) 488–5264, E-mail: *mnw1@cdc.gov.*

Dated: May 6, 2002.

Sandra R. Manning,

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

[FR Doc. 02–12087 Filed 5–14–02; 8:45 am]

BILLING CODE 4063–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0398]

Agency Information Collection Activities; Announcement of OMB Approval; Format and Content Requirements for Over–the–Counter (OTC) Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Format and Content Requirements for Over–the–Counter (OTC) Drug Product Labeling'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 September 27, 2001 (66 FR 49388), 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 0910–0340. The approval expires on April 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 8, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12093 Filed 5–14–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1034]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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 the **Federal Register** of February 8, 2002 (67 FR 5943), 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 0910–0442. The approval expires on April 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 8, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12094 Filed 5–14–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1345]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ACTOS 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions 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.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3565.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Director 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 ACTOS (proglitazone hydrochloride). ACTOS is indicated for the improvement of glycemic control in patients with Type 2 diabetes as monotherapy, or in combination with a sulfonylurea, metformin or insulin when diet and the single agent does not result in adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ACTOS (U.S. Patent No. 4,687,777) 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 January 17, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ACTOS 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 ACTOS is 3,556 days. Of this time, 3,374 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 21, 1989. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 21, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 15, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for ACTOS (NDA 21-073) was initially submitted on January 15, 1999.

3. *The date the application was approved*: July 15, 1999. FDA has verified the applicant's claim that NDA 21-073 was approved on July 15, 1999.

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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by July 15, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 12, 2002. 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 (see **ADDRESSES**). Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be 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: April 22, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02–12092 Filed 5–14–02; 8:45 am]

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