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 6, 2004, (69 FR 25404), 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 February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21748 Filed 9–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0017]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Event Pilot Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adverse Event Pilot Program for Medical Devices'' 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 Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 14, 2004 (69 FR 33034), 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 0910–0471. The approval expires on September 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21750 Filed 9–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0033]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DERMAGRAFT 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 which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/docket/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device DERMAGRAFT. DERMAGRAFT is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than 6–weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. DERMAGRAFT should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Dermagraft (U.S. Patent No. 4,963,489) from Advanced Tissue Sciences, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 10, 2003, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of DERMAGRAFT 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 DERMAGRAFT is 4,050 days. Of this time, 3,650 days occurred during the testing phase of the regulatory review period, while 400 days occurred during the approval phase. These periods of

time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective*: August 29, 1990. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on September 2, 1992. FDA records confirm that one IDE for this medical device did become effective on September 2, 1992. However, FDA records also indicate that another IDE for this medical device was determined substantially complete for clinical studies to have begun on August 29, 1990, which represents the IDE effective date. Although this IDE was for a different indication, it is material to the approval of DERMAGRAFT. FDA considers all investigational exemptions for a particular product to be material to the approval of the product regardless of any difference between the indications studied and those ultimately approved.

2. T*he date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: August 25, 2000. The applicant claims August 24, 2000, as the date the premarket approval application (PMA) for DERMAGRAFT (PMA P00036) was initially submitted. However, FDA records indicate that PMA P00036 was submitted on August 25, 2000.

3. *The date the application was approved*: September 28, 2001. FDA has verified the applicant's claim that PMA P00036 was approved on September 28, 2001.

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 5 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by November 29, 2004. 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 March 28, 2005. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy and 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 30, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–21749 Filed 9–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Citizenship and Immigration Services

Agency Information Collection Activities: Extension of Existing Collection; Comment Request

ACTION: Request OMB Emergency Approval: Request to Enforce Affidavit of Financial Support and Intent to Petition for Custody for Public Law 97–359 Amerasian; Form I–363.

The Department of Homeland Security (DHS), Citizenship and Immigration Services (CIS) has submitted an emergency information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The DHS has determined that it cannot reasonably comply with the normal clearance procedures under this part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. Therefore, OMB approval has been requested by October 31, 2004.

If granted, the emergency approval is only valid for 90 days. ALL comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention: Desk Officer, Department of Homeland Security, 725–17th Street, NW., Suite 10235, Washington, DC 20503; 202–395–5806.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the DHS requests written comments and suggestions from the public and affected agencies concerning this information collection. Comments are encouraged and will be accepted until November 29, 2004. During the 60-day regular review, ALL comments and suggestions, or questions regarding additional information, as well as requests to obtain a copy of the information collection instrument with instructions, should be directed to Mr. Richard A. Sloan, 202–616–7600, Director, Regulatory Management Division, Department of Homeland Security, 111 Massachusetts Avenue, NW., Washington, DC 20529. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Request to Enforce Affidavit of Financial Support and Intent to Petition for Custody for Public Law 97–359 Amerasian.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–363. Citizenship and Immigration Services (CIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is used to determine whether an Affidavit of Financial Support and Intent to Petition for Legal Custody requires enforcement.