

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. *The 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.

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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.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 50 responses at 30 minutes (.50 hours) per response.*

(6) *An estimate of the total public burden (in hours) associated with the collection: 25 annual burden hours.*

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202-616-7600, Director, Regulatory Management Division, Citizenship and Immigration Services, Department of Homeland Security, 111 Massachusetts Avenue, NW., Washington, DC 20529. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

Dated: September 24, 2004.

Richard A. Sloan,

Department Clearance Officer, Department of Homeland Security, Citizenship and Immigration Services.

[FR Doc. 04-21791 Filed 9-28-04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Citizenship and Immigration Services

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

ACTION: Request OMB Emergency Approval; Petition for Nonimmigrant Worker; Form I-129

The Department of Homeland Security, Citizenship and Immigration Services (CIS) has submitted the following 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 (1)(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. Emergency review and approval of this information collection will ensure that the collection may continue. Therefore, OMB approval has been requested by October 31, 2004.

If grant, 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 for sixty days 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, Citizenship and Immigration, U.S. 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 previously approved information collection.*

(2) *Title of the Form/Collection: Petition for Nonimmigrant Worker.*

(3) *Agency form number, if any, and the applicable component of the*

Department of Homeland Security sponsoring the collection: Form I-129, Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as brief abstract: Primary: Individuals or households. This form is used by an employer to petition for aliens to come to the U.S. temporarily to perform services, labor, training or to request extensions of stay or changes in nonimmigrant status for nonimmigrant workers.*

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 368,948 responses at 2.75 hours per response.*

(6) *An estimate of the total public burden (in hours) associated with the collection: 998,357 annual burden hours.*

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan, 202-616-7600, Director, Regulatory Management Division, U.S. Department of Homeland Security, 111 Massachusetts Avenue, NW., Washington, DC 20529. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

Dated: September 24, 2004.

Richard A. Sloan,

Departmental Clearance Officer, U.S. Department of Homeland Security, Citizenship and Immigrant Services.

[FR Doc. 04-21792 Filed 9-28-04; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; OMB Control Number 1018-0111; Summary Information for Ranking National Coastal Wetlands Grant Program Proposals, 50 CFR Part 84

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: The Fish and Wildlife Service (We) has submitted the collection of information listed below to OMB for approval under the provisions of the Paperwork Reduction Act of 1995. If