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 Aldara™ (5,238,944) (imiquimod). Aldara™ (5,238,944) (U.S. Patent No. 5,238,944) is indicated for the treatment of external genital and perianal warts/condyloma acuminata in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Aldara™ (5,238,944) from Riker Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 22, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Aldara™ (5,238,944) 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 Aldara™ (5,238,944) is 3,471 days. Of this time, 3,254 days occurred during the testing phase of the regulatory review period, 217 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:* August 30, 1987. The applicant claims September 1, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 1987, 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:* July 26, 1996. The applicant claims July 25, 1996, as the date the new drug application (NDA) for Aldara™ (5,238,944) (NDA 20–723) was initially submitted. However, FDA records indicate that NDA 20–723 was submitted on July 26, 1996.

3. *The date the application was approved:* February 27, 1997. FDA has verified the applicant's claim that NDA 20–723 was approved on February 27, 1997.

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 187 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 21, 1998, 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 April 19, 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: September 28, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–27995 Filed 10–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Meeting

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of November 1998.

NAME: National Advisory Council on Migrant Health.

DATE & TIME: Thursday, November 12, 1998 at 9:00 a.m. to Friday, November 13, 1998 at 1:00 p.m.

PLACE: Sheraton Springfield, 1 Monarch Place, Springfield, MA 01144, 413/781–1010 (phone) or 413/734–3249 (fax). he meeting is open to the public.

AGENDA: This will be a meeting of the Council. The agenda includes an overview of general Council business activities and priorities. Topics of discussion will include the State Children's Health Insurance Program, Worker Protection Standards, the collaboration possibilities with other migrant health advocate organizations, and the 1998 NACMH Recommendations. In addition, the

Council will be holding its annual Farmworker Public Hearing. The Hearing is scheduled for Friday, November 13 from 8 to 11 a.m. at the Sheraton Springfield.

The Council meeting is being held in conjunction with the 11th Annual East Coast Migrant Stream Forum, November 13–15, 1998. The Stream Forum also will take place at the Sheraton Springfield, Springfield, MA.

Anyone requiring information regarding the subject Council should contact Susan Hagler, Migrant Health Program, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone 301/594–4302.

Agenda items are subject to change as priorities indicate.

Dated: October 14, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–28058 Filed 10–19–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4351–N–09]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: December 21, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW, Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Priscila J. Prunella, 202–708–3700, extension 5711 (this is not a toll free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including if the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of proposed collection of information; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Assessment of the Economic and Social Characteristics of the Low Income Housing Tax Credit (LIHTC) Residents and Neighborhoods.

Description of the need for information and proposed use: The Department is conducting, under contract to Abt Associates Inc., an Assessment of the characteristics of LIHTC Residents and Neighborhoods. The main objective is to understand LIHTC projects in the context of their neighborhoods and the relationship of tax credit tenants to their neighborhoods. Key issues to be examined include: the extent to which residents are similar or different from other neighborhood residents; rent setting practices and the implication of residents' financial characteristics for project financial stability; benefits to the residents of relocating to the implication of residents' financial characteristics for project financial stability; benefits to the residents of relocating to the LIHTC project; residents' perception of the community; and the impact of the LIHTC project on the area itself.

Members of the affected public: Residents sampled in 40 LIHTC properties that are selected for the study.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response; The researchers will administer a one-time, telephone survey to 1,000 residents. The interviews are expected to last 30 minutes for a total burden hour estimate of 500 hours.

Status of the proposed information collection: Pending OMB approval.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: September 29, 1998.

Xavier de Souza Briggs,

Deputy Assistant Secretary for Research, Evaluation, and Monitoring.

[FR Doc. 98–28131 Filed 10–19–98; 8:45 am]

BILLING CODE 4210–62–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4349–N–39]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: November 19, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval