reclassification, FDA is announcing the availability of the draft guidance for premarket notification for the proposed reclassified contact lens care products entitled ''Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.''

II. The Draft Guidance

The draft guidance sets forth the testing that FDA believes ensures the continued safety and effectiveness of transitional contact lens care products. It also provides comprehensive directions to enable a manufacturer of a contact lens care product to submit a 510(k) premarket notification demonstrating substantial equivalence of the device to a legally marketed contact lens care product (predicate device). Information on the battery of preclinical testing that may demonstrate substantial equivalence is included in the guidance. If the results of preclinical testing demonstrate that the device will have new characteristics, clinical performance data may be needed to establish substantial equivalence. If clinical performance data are needed, the guidance document provides suggested methodologies (e.g., size and scope of the study) to be included in the investigational protocol.

The draft guidance also outlines the types of manufacturing and chemistry, toxicology, and microbiology testing that should be completed for each device, and a summary of the basic requirements and suggested methods for meeting these preclinical requirements. Other elements of the draft guidance include: (1) General information on the regulations and requirements for labeling contact lens care products; (2) information about 510(k) requirements relating to modifying a marketed contact lens care product; and (3) guidance for submitting a 510(k) for contact lens cases and contact lens accessories (i.e., mechanical cleaning aids and accessory cleaning pads).

In the event that clinical trials are necessary, FDA emphasizes that manufacturers must conduct the trials in accordance with the investigational device exemption regulations in 21 CFR part 812. At this time, FDA considers clinical studies of most contact lens care products to be nonsignificant risk investigations. For nonsignificant risk investigations, approval of an institutional review board (IRB) is necessary before initiating a clinical study, and an investigational plan and informed consent document must be presented to an IRB for review and approval. Prior FDA approval is not required. However, FDA considers most clinical studies of solutions that contain new active ingredients for ophthalmic use and are intended for use directly in the eye to be significant risk investigations that would require both IRB and FDA review and approval.

This draft guidance will be discussed at a future meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee. The date, time, and place of this meeting will be announced in a future issue of the Federal Register.

III. Significance of a Guidance

In the past, guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, this draft guidance is not being issued under the authority of § 10.90(b). Although this guidance does not create or confer any rights on any person, and does not operate to bind FDA in any way, it does represent FDA's current thinking on the tests the agency believes necessary to provide reasonable assurance of the safety and effectiveness of transitional contact lens care products.

IV. Requests for Comments

Interested persons may, on or before May 31, 1996, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether to amend the current draft guidance.

Dated: March 18, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–7834 Filed 3–29–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3917–N–57]

Office of Administration; Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

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

DATES: The due date for comments is April 8, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, an information collection package with respect to a proposed ''Application Kit for the Campus of Learners Initiative.'' HUD seeks to implement this by April 4, 1996.

Under the Campus of Learners Initiative, HUD will designate between 15 and 20 Campus of Learner sites. Designations will be awarded to public housing authorities (PHAs) that prepare creative strategic plans to provide residents with education, job training, and employment opportunities involving computer and telecommunications technology through a college campus-style setting.

To appropriately determine which PHAs should be awarded Campus of Learner designations, certain information is necessary. The criteria for designation will be PHAs that (1) Are in partnership with local education agencies, State education agencies, institutions of higher education, telecommunications and other businesses, other private-sector partners, child-care providers, community-based organizations, etc; and (2) demonstrate a comprehensive plan for transforming at-risk communities through living and

learning opportunities in a range of education, technology, academic learning, skills, enhancement, leadership and self-esteem development, employment, and entrepreneurial positions for children, youth and families.

This initiative is designed to transform public housing into safe and livable communities where families undertake training in new telecommunications and computer technology and partake in new telecommunications and computer technology and partake in education opportunities and job training initiatives with local businesses.

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):

(1) Title of the information collection proposal: Application Kit—Campus of Learners Initiative.

(2) Summary of the collection of information: Each respondent seeking a Campus of Learners designation would be required to submit current information, as listed below as:

1. Fact Sheet—Information about the respondent: name, address, telephone, facsimile number if joint applicant, same information.
2. Abstract—Brief abstract of the program proposed in the application.
3. Strategic Plan—A narrative describing the activities planned the Campus of Learners Education and Training Initiative.
4. List of Partnerships—List of public, private, State and local sources expected to provide support and funding amount (if committed).
5. Form S.F. 424—Application for Federal Assistance.
6. Form S.F. 424A—Budget Information—Non-Construction Programs.
7. HUD 2880—Applicant/Recipient Disclosure/Update Report.
8. S.F. LLL–A—Disclosure of Lobbying Activities.
9. Certification Assurances with applicable Federal requirements.
10. Certification Regarding Drug-Free Workplace Requirements.

(3) Description of the need for the information and its proposed use:

To appropriately determine which PHAs should be awarded Campus of Learner designations, certain information is necessary. The criteria for designation will be PHAs that (1) are in partnership with local education agencies, State education agencies, institutions of higher education, telecommunications and other businesses, other private-sector partners, child-care providers, community-based organizations, etc.; and (2) demonstrate a comprehensive plan for transforming at-risk communities through living and learning opportunities in a range of education, technology, academic learning, skills, enhancement, leadership and self-esteem development, employment, and entrepreneurial positions for children, youth and families.

(4) description of the likely respondents, including the estimated number of likely respondents, and proposed frequency of response to the collection of information:

Respondents will be public housing authorities (PHA) and partner organizations. It is unlikely that any individual PHA has the expertise or resources to establish a Campus of Learners Initiative by itself. PHA applicants should plan to establish a partnership, or consortium, that includes telecommunications industry representatives, public housing families, local education agencies, institutions of higher learning, religious organizations, nonprofit community-based organizations, and/or other eligible organizations or private-sector entities.

The estimated number of respondents is 75. The proposed frequency of the response to the collection of information is one-time. The application need only be submitted once.

(5) Estimate of the total reporting and recordkeeping burden that will result from the collection of information:

Reporting Burden

Number of respondents: 75.

Total burden hours (@ 7.5 hour per response): 562.50.

Total Estimated Burden Hours: 562.50.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 25, 1996.

David S. Cristy,

Director, IRM Policy and Management Division.

[FR Doc. 96–7920 Filed 3–29–96; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of Application for Incidental Take Permit for Construction of Park 22, a 32-Acre Commercial Development on RR 2222 in Travis County, Texas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Park 22 Joint Venture has applied to the Fish and Wildlife Service for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act. The applicant has been assigned permit number PRT–807192. The requested permit, which is for a period of 30 years, would authorize the incidental take of the endangered golden-cheeked warbler (Dendroica chrysoparia). The proposed take would occur as a result of the construction of a commercial development on RR 2222 in Travis County, Texas.

The Fish and Wildlife Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take application. A determination of whether jeopardy to the species will result from issuance of this permit, or a Finding of No Significant Impact (FONSI) will not be made before 30 days from the date of publication of this notice. The notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before May 1, 1996.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Joseph E. Johnston or Sybil Vosler, Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0063). Documents will be available for public inspection during normal business hours (8:00 to 4:30), U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCPs should be submitted to the Field Supervisor, Ecological Services Field Office, Austin, Texas (see address above). Please refer to permit number PRT–807192 when submitting comments.