OMB Comment: Consideration will be given to comments and suggestions received within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: March 26, 1996.

Roberta Katson,

Director, Office of Information Resource Management Services.

[FR Doc. 96–7788 Filed 3–29–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 93F–0483]

Rio Linda Chemical Co., Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of that portion of a food additive petition (FAP 2A4408) proposing that the food additive regulations be amended to provide for the safe use of chlorine dioxide to disinfect waters contacting fresh meat, processed meat, and processed poultry.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of February 2, 1994 (59 FR 4924), FDA announced that a food additive petition (FAP 4A4408) had been filed by Rio Linda Chemical Co., Inc., 410 North 10th St., Sacramento, CA 95814 (currently, 1902 Channel Dr., West Sacramento, CA 95691–3477). The petition proposed to amend the food additive regulations to provide for the safe use of chlorine dioxide to disinfect waters contacting fresh meat, fresh poultry, processed meat, and processed poultry. FDA published a final rule in the Federal Register on March 3, 1995 (60 FR 11899), approving the use of chlorine dioxide in process water contacting whole fresh poultry (21 CFR 173.69).

Rio Linda Chemical Co., Inc., has now withdrawn that portion of the petition that relates to the use of chlorine dioxide to disinfect waters contacting fresh meat, processed meat, and processed poultry without prejudice to a future filing (21 CFR 171.7).

Dated: March 18, 1996.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–7785 Filed 3–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0399]

Medical Devices; Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.'' The draft guidance accompanies a proposed rule to reclassify rigid gas permeable contact lens solution; soft (hydrophilic) contact lens solution; and contact lens heat disinfecting units from class III (premarket approval) to class II (special controls), which appears elsewhere in this issue of the Federal Register. The draft guidance sets forth the tests FDA's Center for Devices and Radiological Health (CDRH) believes necessary to provide reasonable assurance of the safety and effectiveness of these devices. The draft guidance also sets forth the evidence that FDA believes should be submitted to demonstrate the substantial equivalence of new contact lens care products to contact lens care products already marketed.

DATES: Submit written comments by May 31, 1996.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products'' to the Division of Small Manufacturers Assistance (HFZ–22O), CDRH, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2205.

SUPPLEMENTARY INFORMATION:

I. The Statutory Requirements

The Safe Medical Devices Act (the SMDA) (Pub. L. 101–629), which amended the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et. seq.*), contains specific provisions on transitional devices (i.e., those devices regulated as new drugs before the Medical Device Amendments of 1976 (Pub. L. 94–295) became law). See section 520(l) of the act (21 U.S.C. 360j(l)). In 1976, Congress classified all transitional products, including rigid gas permeable contact lens solutions; soft (hydrophilic) contact lens solutions; and contact lens heat disinfecting units into class III (premarket approval). The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III. H. Rept. 808, 101st Cong., 2d sess. 26-27 (1990); S. Rept. 513, 101st Cong., 2d sess. 26-27 (1990). Congress amended section 520(l) of the act to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices and review the classification of those transitional devices that still remained in class III to determine if the devices should be reclassified into class II (special controls) or class I (general controls).

Under section 520(l)(5)(B) of the act, FDA was to publish regulations by December 1, 1992, either leaving the transitional class III devices in class III or revising their classification down to class I or class II. However, as permitted by section 520(l)(5)(C) of the act, in the Federal Register of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish regulations before the December 1, 1993 deadline. Nevertheless, elsewhere in this issue of the Federal Register, FDA is proposing to reclassify from class III (premarket approval) to class II (special controls) all transitional contact lens care products. In conjunction with the proposed

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