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Rio Linda Chemical Co., Inc., has now withdrawn that portion of the petition that relates to the use of chlorine dioxide to disinfect waters contacting fresh meat, processed meat, and processed poultry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