public display in the Dockets Management Branch under Docket No. 95S–0135. Updated information related to patents on animal drug products will be placed on public display in the **Dockets Management Branch under** Docket No. 95S–0126. Updated patent information for human drug products will be published in the monthly supplements to "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) and updated patent information for animal drug products will be published in the monthly supplements to "FDA Approved Animal Drug Products" (the Green Book) after June 8, 1995.

III. Amended Patent Certifications

Abbreviated new drug applications (ANDA's), abbreviated new animal drug applications (ANADA's), and applications provided for in section 505(b)(2) of the act (505(b)(2) applications) pending before the agency on June 8, 1995, including such applications that may have received tentative approval letters, must be amended to respond to the URAAextended patent expiration dates, if information on the new expiration dates is submitted to the agency by the NDA or NADA holder in a timely manner. ANDA's, ANADA's, and 505(b)(2) applications submitted after June 8. 1995, likewise must provide patent certifications with respect to the URAAextended patent expiration dates. After June 8, 1995, FDA will not approve any application that does not contain a correct certification with respect to a URAA-extended patent expiration date that was submitted in a timely manner to the agency. The agency expects that an applicant that wishes to market a drug under an approved ANDA, ANADA, or 505(b)(2) application before the expiration of a URAA-extended patent, for which information was submitted to FDA in a timely manner, will file a paragraph IV certification with respect to that patent (See sections 505(b)(2)(A), (j)(2)(A)(vii), and 512(n)(1)(H) of the act.)

Amended patent certification statements for abbreviated new drug applications (ANDA's) and 505(b)(2) applications reviewed by the Office of Generic Drugs should be sent to the Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Amended patent certification statements for 505(b)(2) applications reviewed by the new drug reviewing divisions within CDER should be sent to the appropriate review division. Amended patent certification statements pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV–199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Amended patent certification statements pertaining to biological products should be sent to the Document Control Center, Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

Dated: June 2, 1995.

William B. Schultz,

Deputy Commissioner for Policy. [FR Doc. 95–14060 Filed 6–5–95; 2:29 pm] BILLING CODE 4160–01–F

[Docket No. 95M-0119]

Chartex International plc; Premarket Approval of Femidom® Female Condom

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Chartex International plc, London, U.K., for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Femidom® Female Condom. The device is to be manufactured under an agreement with Wisconsin Pharmacal Co., Inc., Jackson, WI, which has authorized Chartex International plc to incorporate information contained in its approved premarket approval application for the RealityTM Female Condom (P910064). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 14, 1995, of the approval of the application. **DATES:** Petitions for administrative review by July 10, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION: On September 30, 1994, Chartex International plc, London, U.K., submitted to CDRH an application for

premarket approval of the Femidom® Female Condom. The device is an intravaginal barrier device and is indicated for use to help prevent pregnancy and sexually transmitted diseases (STD's), including the human immunodeficiency virus (HIV) infection during vaginal intercourse. The application includes authorization from Wisconsin Pharmacal Co., Inc., Jackson, WI, 53037, to incorporate information contained in its approved premarket approval application for the Reality[™] Female Condom (P910064). In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On April 14, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be