Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6630. Programmatic technical assistance may be obtained from Timothy Thornton, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop K–60, Atlanta, GA 30333, telephone (404) 488–4389.

Please refer to Announcement 548 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: June 1, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–14044 Filed 6–7–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket Nos. 95P–0061, 95S–0117, 95S–0126, and 95S–0135]

Patent Term Extensions Under the Uruguay Round Agreements Act and Their Effects on Marketing Applications for Human and Animal Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its response to a citizen petition from Glaxo Pharmaceuticals, Inc. (Glaxo). The petition requested that the agency announce how the Uruguay Round Agreements Act (URAA) will affect the patent information submission and patent certification requirements for applications to market drug products under the Federal Food, Drug, and Cosmetic Act (the act). FDA responded to the petition on May 25, 1995. The response provides applicants with current information on how the URAA will affect patent term extension requirements for applications to market human and animal drugs.

DATES: Amended patent information, reflecting any extended patent terms under the URAA, should be submitted to FDA before July 8, 1995, but no earlier than June 8, 1995.

ADDRESSES: Copies of the citizen petition (95P–0061/CP1), comments submitted to FDA regarding the citizen petition, and FDA's response to the citizen petition may be obtained from the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857. Copies are also available for public examination at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: On December 8, 1994, the URRA (Pub. L. 103–465) was signed into law. The URAA made amendments to Title 35 of the United States Code. These amendments relate to patent terms for existing and future patents, and they will become effective on June 8, 1995. Certain provisions of the URAA patent amendments will change the terms of some existing patents from 17 years from the date of the granting of the patent to 20 years from the filing of the patent application.

On February 16, 1995, the Patent and Trademark Office (PTO) held a public hearing on the patent provisions amended by the URAA. The PTO devoted a portion of the hearing to addressing several issues pertaining to the effect of these changes in patent law on FDA's enforcement of the act. (See the **Federal Register** notice of January 17, 1995 (60 FR 3398).) Oral testimony was given at the hearing and written submissions were made to PTO and FDA. Glaxo submitted its citizen petition to FDA on March 7, 1995. The petition requested that the agency announce the effect the URAA will have on the patent information submission and patent certification requirements for applicants to market drug products under the act. FDA has received a number of responses to Glaxo's citizen petition from generic and innovator drug manufacturers. Glaxo submitted an additional comment on the responses dated April 13, 1995. These documents are included in Docket No. 95P–0061. These oral and written submissions were considered by FDA in developing its response to the petition.

A brief summary of FDA's position on patent term extensions under the URAA is set out below in this document. A fuller exposition of the agency's position may be found in the response to Glaxo's petition.

I. Submission of Patent Information

FDA has determined that if the patent term expiration date for a listed human or animal drug product is extended by the URAA, the new drug application (NDA) or new animal drug application (NADA) holder must submit information on the new patent term expiration date to FDA after June 8, 1995, but before July 8, 1995. NDA holders who have already submitted information indicating that listed patents will be extended by the URAA should resubmit this information on or after June 8, 1995.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act (21 U.S.C. 355) by the Center for Drug Evaluation and Research (CDER) should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number. Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by the Center for Biologics Evaluation and Research (CBER) 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.

To expedite the availability to the public of the updated patent information, a third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either CDER or CBER should be sent to the Drug Information Services Branch, Center for Drug Evaluation and Research, Food and Drug Administration (HFD–84), 5600 Fishers Lane, Rockville, MD 20857.

Amended patent information 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.

II. Public Availability of Updated Patent Information

Updated information related to patents on human drug products regulated by CDER will be placed on public display in the Dockets Management Branch (address above) under Docket No. 95S–0117, after June 8, 1995. Updated information related to patents on human drug products regulated by CBER will be placed on

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 URAA-extended 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 URAA-extended 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 Reality™ 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