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).

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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