## Patent and Trademark Office

Notice of Hearing and Request for Comments on Changes to a Twenty-Year Patent Term and Its Effects on Patent Expiration Dates and Patent Term Extensions

**AGENCY:** Patent and Trademark Office, Commerce.

**ACTION:** Notice of public hearing and request for comments.

SUMMARY: In a Notice published on December 21, 1994 [59 FR 63951], the Patent and Trademark Office ("PTO") announced a public hearing on proposed changes related to the 20-year patent term contained in the Uruguay Round Agreements Act ("URAA"), Pub. L. 103–465.

Concurrently with the hearing scheduled for February 16, 1995, PTO also seeks comments on several additional issues that are relevant to the Food and Drug Administration's interpretation and application of current provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations in light of the changes to title 35, United States Code, effected by passage of the URAA. The specific provisions of the FDCA that would be affected govern the submission of patent information related to new drug applications ("NDAs") and the submission and approval of abbreviated new drug applications ("ANDAs") for generic equivalents of listed drugs in anticipation of the expiration of patent protection for the listed drugs. (See 21 U.S.C. 321; 21 CFR part 314, subparts C and D.) Similarly affected may be FDCA provisions related to the submission of new animal drug applications ("NADAs") and the submission and approval of abbreviated new animal drug applications ("ANADAs"). (See 21 U.S.C. 360b). Because the changes to title 35 may affect the effective date of ANDA and ANADA approval under the FDCA and are relevant to the issues that will be discussed at the public hearing to be held on February 16, 1995, PTO will set aside a portion of the meeting to address these issues.

In addition, PTO seeks comments on the URAA's effect on existing patent term extensions under 35 U.S.C. 156. DATES: The public hearing will be held on February 16, 1995, at 9:30 a.m. in the Commissioner's Conference Room 912, Crystal Park 2, 2121 Crystal Drive, Arlington, Virginia. Oral testimony on issues addressed in this notice will begin at 1:00 p.m. Requests to present oral testimony should be received on or before February 14, 1995. Written

comments must be submitted on or before February 17, 1995.

**ADDRESSES:** Address written comments and requests to present oral testimony to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, Attention: Stephen G. Kunin, Deputy Assistant Commissioner for Patent Policy and Projects, Crystal Park 2, Suite 919, or by fax to (703) 305-8825. Persons with comments on the issues raised in this notice should also forward copies of those comments to the Food and Drug Administration, Attention: Dockets Management Branch (HFA-305), Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857, identified with docket number 95N-0005.

FOR FURTHER INFORMATION CONTACT: H. Dieter Hoinkes by telephone at (703) 305–9300, by fax at (703) 305–8885, through electronic mail to hoinkes@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231. Persons may also contact Brain Malkin by Phone at (301) 443–1382, by fax at (301) 443–0232 or by mail marked to his attention and addressed to the Food and Drug Administration, Office of Health Affairs, HFY–20, 5600 Fishers Lane, Rockville, MD 20857.

## SUPPLEMENTARY INFORMATION:

## I. The Effect of URAA on the FDCA's ANDA Approval Process

Background

As described in detail in the Federal Register notice published on December 12, 1994, the URAA was signed into law on December 8, 1994 (Pub. L. 103-465). The amendments to title 35, United States Code, in the URAA that relate to patent terms will become effective June 8, 1995. Certain provisions of the URAA patent amendments will change the term of existing patents from 17 years from the date of patent grant to 20 years from the date of filing of the patent application. If the patent application contains a specific reference to an earlier application under 35 U.S.C. 120, 121 or 365(c), the patent term will end 20 years from the date on which the earliest application relied on was filed. Patents that are in force on, or applied for by, June 8, 1995, will be entitled to the longer of 17 years from the date of the grant of the patent, or 20 years from the date of filing of the application. In addition, the URAA patent amendments provide for the extension of patents (up to a maximum of five years) in certain specified instances where there was delay in the issuance of the patent. This extension is separate from, and in

addition to, the patent term extension available under 35 U.S.C. 156.

Section 532(c)(2) of the URAA patent amendments also limits the remedies available to a patent holder for patent infringement under certain circumstances. Specifically, a patent holder may not obtain an injunction or monetary damages, currently provided under title 35, for "acts which (A) were commenced or for which substantial investment was made before [June 8. 1995] and (B) became infringing by reason of [any amendment to a patent term resulting from the new 20-year provision]." Instead, the patent holder may only collect an "equitable remuneration" under such circumstances.

These amendments to title 35 may affect the drug approval process. Under the FDCA, pharmaceutical companies seeking to market pioneer drugs must first obtain FDA approval through the filing of an NDA (see, 21 U.S.C. 355(a) and (b)). In addition to data demonstrating the safety and effectiveness of the drug, an NDA applicant is required to submit to FDA information on any patent which claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party (see, 21 U.S.C. 355(b)(1) and (c)(2). The patent information must include the patent number and date of expiration. FDA publishes this required information in its official publication, Approved Drug Products With Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book").

Under section 505(j)(2)(A)(vii) of the FDCA (21 U.S.C. 355(j)(2)(A)(vii)), an ANDA must include a certification, in the opinion of the applicant and to the best of the applicant's knowledge with respect to each patent which claims the listed drug, (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. In addition, an ANDA applicant, who certifies that a patent is either invalid or will not be infringed, must provide notice of this filing to each owner of the patent as well as to the holder of the approved NDA for the listed drug which is claimed by the patent (see 21 U.S.C. 355(j)(2)(B)(i)). This notice must contain a statement of the legal and factual grounds that support the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed