(see 21 U.S.C. 355(j)(2)(B)(ii); 21 CFR 314.52(c)(6)).

Under the FDCA, an ANDA approval shall be made effective on the date certified by the ANDA applicant to be the date on which a patent expires (see 21 U.S.C. 355(j)(4)(B)(ii)), or immediately if certified by the ANDA applicant (1) that patent information has not been filed or that the patent has expired (see 21 U.S.C. 355(j)(4)(B)(i)); or (2) that the patent is invalid or will not be infringed, unless an action is brought within 45 days after the ANDA applicant gives notice to the patent holder under section 505(j)(2)(B)(i) of the FDCA (see 21 U.S.C. 355(j)(4)(B)(iii)).

The FDCA and implementing regulations provide no other mechanism by which to stay the effective date of an

ANDA approval.

Under the FDCA, similar provisions apply to NADAs and ANADAs. Upon the approval of an NADA, FDA publishes required NADA patent information in its official publication, FDA Approved Animal Drug Products (referred to as the "Greek Book"). (See 21 U.S.C. 360b(b)(1)). ANADAs are subject to patent certification requirements (see 21 U.S.C. 360b(n)(1)(H)) and to approval effective dates (see 21 U.S.C. 360b(c)(2)(D)), similar to the ANDA provisions described above. The effective approval date of an ANADA, similar to an ANDA, is stayed only if an action is brought within 45 days after the ANADA applicant gives notice to the patent holder under 21 U.S.C. 360(n)(2)(B)(i), that the patent is not valid or will not be infringed. The FDCA provides no other mechanism by which to stay the effective date of an ANADA.

Issues Upon Which Comments Are Sought

Comments are requested regarding the effect of the URAA patent amendments upon the filing and approval of ANDAs and ANADAs. Specifically, comments are requested on the following questions:

1. Should FDA revised the patent term expiration dates currently listed in the Orange Book and Green Book for those patents entitled to a longer term under the URAA, because they are in force on June 8, 1995?

2. Should PTO, at the request of NDA or NADA holders, certify (or alternatively, verify) new patent expiration dates under the URAA for patents currently listed in the Orange Book and the Green Book?

3. Should NDA and NADA holders be required to submit to FDA revised patent expiration dates for those patents

currently listed in the Orange Book and Green Book that will have a longer term under URAA? If so, should such submissions be required to be made (1) by June 8, 1995, (2) only after PTO certifies or verifies the claimed patent term expiration date, or (3) within some other specified time period?

4. If revised patent term expiration dates are published in the Orange Book and the Green Book, then if PTO does not certify or verify the patent term expiration date identified by the NDA or NADA holder, what submission, if any, should FDA require to verify the date? Should FDA publish the revised patent term expiration date submitted by the NDA or NADA holder without verification?

5. If revised patent term expiration dates are published in the Orange Book and the Green Book, what revisions to patent certifications, if any should applicants with pending ANDAs or ANADAs be required to make? When should such revisions to patent certifications be made? What type of information related to substantial investment, if any, should ANDA and ANADA applicants be required to make with such revisions?

II. The Effect of URAA on Existing Patent Term Extensions Under 35 U.S.C. 156

Under 35 U.S.C. 156, patent term extensions are issued for eligible patents from the original expiration date of the patent. Since this provision was enacted in 1984, the PTO has issued 195 certificates of patent term extension in accordance with section 156. Under the URAA, patents in force on June 8, 1995, are entitled to a patent term of 17 years from grant or 20 years from filing, whichever is longer. The PTO estimates that 93 patents whose terms were extended under section 156 would be entitled to such longer patent term. The PTO has assumed, for the purpose of evaluating the number of extending patents that may be affected by the 20year patent term, that a patent that would have expired (under the original 17-year patent term) before June 8, 1995, but has received a patent term extension for a period beyond June 8, 1995 (with the rights prescribed in 35 U.S.C. 156(b)), is a patent "in force" on June 8, 1995.

There are several ways to interpret the provision of the URAA that grants the longer of a 17 or 20-year patent term to patents in force on June 8, 1995, and that have been or will be extended under section 156. First, the extension already issued by the PTO could simply be added to the longer of the 17 or 20-year patent term. No action would be

required by the PTO. Second the extension already issued by the PTO could be interpreted to operate from "the original expiration date of the patent" (35 U.S.C. 156(a)), which could be interpreted as the expiration date of the 17-year patent term. Again, no action would be required by the PTO. A third interpretation could be that the appropriate extension under section 156 would be added to the longer of the 17 or 20-year patent term. This third interpretation would require the PTO to revise the extension granted in some cases as the 14-year limitation of a patent term counted from the date of market approval (35 U.S.C. 156(c)(3)) would be applicable to the extended patent term regardless of whether the original expiration date of the patent was 17 years from grant or 20 years from the filing date. The PTO seeks comments from the public on the appropriate course of action with respect to patents that have been or will be issued term extensions under section 156 of title 35, United States Code.

Questions

1. Should PTO take any action with respect to existing patent term extensions under section 156?

2. What approach should PTO take with respect to the calculation of new patent term extensions under section 156 where the patent is entitled to the longer of the 17 or 20-year patent term under the URAA?

Comments on any other issues relevant to the relationship between the URAA and the FDCA or existing patent term extensions under 35 U.S.C. 156 are also invited.

Dated: January 11, 1995.

Michael K. Kirk,

Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks.

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COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Wool Textile Products Produced or Manufactured in the Slovak Republic; Correction

January 10, 1995.

The letter to the Commissioner of Customs published in the **Federal Register** on December 16, 1994 (59 FR 65019) should be corrected as follows:

1. In column 2, paragraph 1, line 3, change "June 10, 1993" to read "June 7, 1994."