



SEP -2 2005

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

The attached application for patent term extension of U.S. Patent No. 5,852,195 was filed on August 16, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, APTIVUS® (tipranavir), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, it is noted that the structural formula on page 2 of the application does not unambiguously show the 6R stereochemistry of the active ingredient tipranavir. The structural formula on the first page of Exhibit A, Copy of Approved Labeling for APTIVUS® Capsules, is considered to show the correct stereochemistry.

Inquiries regarding this communication should be directed to the Kathleen Kahler Fonda, Legal Advisor, at (571) 272-7754 (telephone).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

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