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

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached applications for patent term extension of U.S. Patent No. 5,376,634 were filed on May 13, 2005, under 35 U.S.C. § 156. Both applications were filed for the above-identified patent, with one application being based upon NDA 21-506, and the other based upon NDA 21-754.

The assistance of your Office is requested in confirming that the products identified in the applications, Mycamine™ (micafungin sodium)(NDA 21-506 and NDA 21-754), have 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. As stated on page 29 of the application for patent term extension, it is noted that applications for patent term extension were also filed for U.S. Patent No. 6,107,458 and 6,265,536.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7744 (telephone) or (571)273-7744 (facsimile).

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

cc: Oblon, Spivak, McClelland, Maier & Neustadt  
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