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

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 4,840,896 was filed on November 20, 2000, under 35 U.S.C. § 156. The delay in forwarding the application papers is regretted.

The assistance of your Office is requested in confirming that the product identified in the application, Ovidrel® (choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG)), 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).

On the table "NDA Approvals for Calendar Year 2000" (posted at: <http://www.fda.gov/cder/rdmt/NDAAPS00CY.HTM>), the product Ovidrel® was indicated as chemical type 3, new formulation, suggesting that an active ingredient thereof had been previously approved for commercial marketing or sale. If the approval of Ovidrel® was not the first permitted commercial marketing or sale of choriogonadotropin alfa, then the patent may still be eligible for extension if the permission for commercial marketing or sale of choriogonadotropin alfa is the first permitted commercial marketing or use of a product manufactured under the process claimed in the above-identified patent.

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.

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: Roger L. Browdy  
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