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Food and Drug Administration  
Rockville, MD 20857

May 12, 2004

Norman D. LaFrance  
Celltech Americas, Inc.  
755 Jefferson Road  
P.O. Box 31710  
Rochester, New York 14603-1710

Dear Mr. LaFrance:

Your petition requesting the Food and Drug Administration to require an additional bioequivalence test for Metadate CD (methylphenidate HCl, USP), extended release capsules, was received by this office on 05/07/2004. It was assigned docket number 2004P-0225/CP 1 and it was filed on 05/07/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega, Deputy Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management

