



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

July 17, 2006

Joseph A. Carrado, M.Sc., R.Ph  
Duramed Research, Inc.  
One Belmont Avenue  
11th Floor  
Bala Cynwyd, Pennsylvania 19004

Dear Dr. Carrado:

Your petition requesting the Food and Drug Administration to Refrain from Granting any Bioequivalence Waiver for any ANDA Referencing Duramed's NADA 21-544 for Seasonale, was received by this office on 07/14/2006. It was assigned docket number 2006P-0285/CP1 and it was filed on 07/14/2006. 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  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P-0285

Act 1