



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

August 3, 2005

FILE COPY

Chang Lee, MD, MSHA, DrPh
Vice President, Regulatory Affairs
Morton Grove Pharmaceuticals, Inc.
6541 West Main Street
Morton Grove, IL 60053

Dear Dr. Lee:

Your petition requesting the Food and Drug Administration to declare that Warfarin Sodium Solution for oral administration is suitable for submission as an abbreviated new drug application was received by this office on 08/03/2005. It was assigned docket number 2005P-0307/CP 1 and it was filed on 08/03/2005. 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,

A handwritten signature in cursive script that reads "Lyle D. Jaffe".

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0307

ACK 1