



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

October 5, 2004

**FILE COPY**

Wei-wei Chang, Ph.D., President  
NuTec Incorporated  
134 St. Botolph Street  
Boston, MA 02115-4819

Dear Dr. Chang:

Your petition requesting the Food and Drug Administration to determine that Carbinoxamine Maleate chewable drug product, in a 4 mg per tablet strength, is suitable for submission as an ANDA, was received by this office on 10/5/2004. It was assigned docket number 2004P-0451/CP 1 and it was filed on 10/5/2004. 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,

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

2004P-0451

ACK 1