



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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MAR 24 2006

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

Docket No: 2004P-0451/CP1

Dear Dr. Chang:

Reference is made to your petition requesting the Food and Drug Administration to declare that Carbinoxamine Maleate Chewable Tablets are suitable for submission in an ANDA.

FDA has been unable to reach a decision on your request because it raises complex issues requiring extensive review by Agency officials. We will respond to your petition as soon as we have reached a decision.

Sincerely,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

2004P-0451

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