



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

July 26, 2005

Mr. Charles J. Raubicheck
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151

FILE COPY

Dear Mr. Raubicheck:

Your petition requesting the Food and Administration to refuse to approve ANDA or Section 505(b)(2) for inhalation drug products containing a combination of the active ingredients albuterol sulfate and ipratropium hydrochloride, administered by nebulization for the treatment of chronic pulmonary obstructive disorder, was received by this office on 07/25/2005. It was assigned docket number 2005P-0291 CP 1 and it was filed on 07/26/2005.

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,

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

2005P 0291

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