



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

July 20, 2004

FILE COPY

Ms. Michelle A. Carpenter
Dey, L.P.
2751 Napa Valley Corporate Drive
Napa, California 94558

Dear Ms. Carpenter:

Your petition requesting the Food and Drug Administration to determine that ANDA 76-724 filed by Ivax Pharmaceuticals, Inc. for a generic formulation of DuoNeb is subject to a 30-month stay of final approval, was received by this office on 07/16/2004. It was assigned docket number 2004P-0324/CP 1 and it was filed on 07/20/2004. 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 matter in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink that reads "Lyle D. Jaffe".

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

2004P-0324

ACK 1