



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 30, 2001

Marianne Robb
Manager, Regulatory Affairs
Mallinckrodt, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Ms. Robb:

Your petition requesting the Food and Drug Administration to determine that Hydrocodone Bitartrate and Acetaminophen Oral Solution, 10 mg/500 mg per 15 mL is suitable for submission as an Abbreviated New Drug Application, was received by this office on 05/29/01. It was assigned docket number 01P-0251/CP 1 and it was filed on 05/29/01. 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,


Gloria Ortega

Dockets Management Branch

01P-0251

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