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October 2, 2001

Elizabeth A. Ernst
Associate Director, Regulatory Affairs
Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228

Dear Ms. Ernst:

Your petition requesting the Food and Drug Administration to determine that Digoxin Elixir, 0.05 mg/mL is suitable for consideration in an abbreviated new drug application was received by this office on 10/02/01. It was assigned docket number 01P-0449/CP 1 and it was filed on 10/02/01. 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,

A handwritten signature in cursive script, reading "Lyle D. Jaffe", is written over the typed name.

Lyle D. Jaffe
Dockets Management Branch

01P-0449

ACK 1