DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

October 17, 2001

Linda Ballia Fischer
Director, Regulatory Affairs
Elan Pharmaceuticals, Inc.
45 Horse Hill Road
Cedar Knolls, NJ 07927-2003

Dear Ms. Fischer:

Your petition requesting the Food and Drug Administration to require an acceptable in vivo bioequivalence study conducted under fasting and fed conditions as a requirement for approval of an abbreviated new drug application for In generic version of Skelaxin (metaxalone) Tablets, 400 mg. was received by this office on 10/17/01. It was assigned docket number 01P-0481/CP 1 and it was filed on 10/17/01. 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,

Lyle D. Jaffe
Dockets Management Branch

01P-0481

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