

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20-353/S-001

APPROVAL LETTER

NDA 20-353/S-001

9.1
MAR 28 1996

Elan Pharmaceutical Research Corporation
Attention: Sharon L. Hamm, Pharm.D., R.Ph.
1300 Gould Drive
Gainesville, Georgia 30504-3947

Dear Dr. Hamm:

Please refer to your February 15, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NAPRELAN (naproxen sodium tablets) CONTROLLED-RELEASE TABLETS, 375 mg, 500 mg, and 750 mg.

We acknowledge receipt of your amendments dated March 5, and 11, 1996.

The supplemental application provides for the deletion of "Due to the gastric pH elevating effects of H₂-blockers, sucralfate, and intensive antacid therapy, concomitant administration of NAPRELAN is not recommended." in PRECAUTIONS, Drug Interactions subsection of the labeling.

We have completed the review of this supplemental application as amended and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the printed labeling submitted on March 11, 1996 with the removal of the sentence, "Due to the gastric pH elevating effects of H₂-blockers, sucralfate, and intensive antacid therapy, concomitant administration of NAPRELAN is not recommended." Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted on March 11, 1996 with the revision identified above.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING for approved supplemental NDA 20-353/S-001." Approval of this labeling by FDA is not required before it is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Please submit one market package of the drug when it is available.

At this time, we are requesting at the next printing or within six months, whichever comes first, that the following revision be made:

The use of the established name "naproxen sodium tablets," should be incorporated in both the labels and labeling.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Sue-Ching Lin
Project Manager
(301) 827-2090

Sincerely yours,

MAC 3/25/96

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc: NDA-20-353
HF-2/MedWatch
HFD-80
HFD-240
HFD-550/DivDir/Chambers
HFD-550/MO/KJohnson
HFD-550/CHEM/BHo
HFD-550/Pharm/WCoulter
HFD-550/Clin/MChang
HFD-550/CSO/SLin
HFD-550/RJoyce
HFD-638
HFD-880/Bashaw
draft:/March 19, 1996/NDA/20353ap.wp
R/D initials by: RJoyce- 3/20/96
Revised 3/27/96 by RDJoyce
Revised 3/28/96 by Chambers

APPROVAL