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APPLICATION NUMBER: NDA 20-353/S-001

MEDICAL REVIEW(S)

Clinical Review of NDA
Labeling Supplement

MAR 27 1996

NDA 20-353/S-001

Submission Date: February 15, 1996
March 5, 1996
March 11, 1996
Review Date: March 27, 1996

Applicant: Elan Pharmaceutical Research Corp.
Gainesville, GA 30504-3947

Applicant's Representative: Sharon L. Hamm, Pharm.D.,R.Ph.
(770) 534-8239

Drug: NAPRELAN (naproxen sodium tablets) CONTROLLED-
RELEASE Tablets, 375 mg, 500 mg and 750 mg

Pharmacologic Category: NSAID

Submitted: Draft labeling to remove the statement "Due to the gastric pH elevating effects of H₂-blockers, sucralfate, and intensive antacid therapy, concomitant administration of NAPRELAN is not recommended."

Comments: This labeling was reviewed against the final printed labeling dated March 11, 1996 which was in response to the approval letter of January 5, 1996, that approved the NDA.

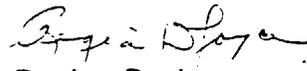
The following discrepancies were found:

1. Under Precautions, subsection Hepatic Effects, third sentence, the word test was added after "The ALT (SGPT) test is probably the most sensitive indicator of liver dysfunction."
2. Under Precautions, subsection Drug Interactions, last paragraph, last sentence the statement "Due to the gastric pH elevating effects of H₂-blockers, sucralfate, and intensive antacid therapy, concomitant administration of NAPRELAN is not recommended." is still in the labeling.
3. Under Adverse Reaction, Incidence less than 1% (Probable Causal Relationship), Special Senses, first sentence the words "ear disorder" appears at the end and is a repeat.

I called Sharon Hamm on March 27th to clarify these discrepancies. I asked her to use the package insert that they had printed that was going out with the product. This insert has the code CI4685-2 and Rev. 021596 on it. Discrepancy #1 the word "test" is not in the insert; #2 the sentence is deleted from the paragraph as requested; and #3 the words "ear disorder" is not repeated.

Recommendation:

A biopharm review has been done stating that the removal of the requested section is acceptable. This labeling may now be approved with a request in the letter that at the next printing, or within six months, whichever comes first, that the established name "naproxen sodium tablets" be incorporated into the package insert.


Regina D. Joyce


Wiley A. Chambers, M.D.

cc: NDA 20-353
HFD-550
HFD-550/SMO/Chambers
HFD-550/Chem/Yaciw
HFD-550/Pharm/Chen
HFD-550/CSO/Lin
HFD-550/Clin/Joyce
HFD-550/Clin/Chang