NDA 19-645

DEC 20 1991

Syntex Research
3401 Hillview Avenue, P.O. Box 10850
Palo Alto, California 94303

Attention: Carol C. Grundfest
Regulatory Program Director
Human Pharmaceutical Regulatory Affairs

Dear Ms. Grundfest:

Please refer to your new drug application, dated October 10, 1986, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toradol (ketorolac tromethamine) Oral Tablet. We also refer to your numerous amendments, including that of December 20, 1991 which included draft labeling.

We have completed the review of this 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 draft labeling submitted on December 20, 1991, with the enclosed revisions. Accordingly, the application is approved effective as of the date of this letter.

Please submit twelve copies of the final printed labeling (FPL) as soon as possible. This submission should be designated for administrative purposes as "FPL for approved NDA 19-645." Approval of this labeling by FDA is not required before the labeling is used. The final printed labeling (FPL) must be identical to the draft labeling enclosed.

We also note your commitment to perform bioequivalence studies on the three crystalline forms of ketorolac.

As a reflection of our mutual understanding of the importance of initial promotional campaigns on physicians' use of new drugs, we note your commitment to work with us and with the Division of Drug Marketing, Adverising and Communication on this advertising program to develop an introductory campaign satisfactory to all concerned. Please submit, prior to implementing, one copy to this division and a second, along with a copy of the package insert, directly to:

Division of Drug Marketing, Advertising and
Communication, HFD-244
Room 10B-04
5600 Fishers Lane
Rockville, Maryland 20857

Please submit all proposed materials in draft or mock-up form, not final print. Also, please do not use form FD-2253 for this submission. This form is for routine use, not proposed materials.

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

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

Sincerely yours,

Review Team
Pilot Drug Evaluation Staff, HFD-007
Center for Drug Evaluation and Research

John G. Harter, M.D. 12-20-91
Director

Patricia Love, M.D.
Medical Officer

Dennis Bashaw 12-20-91
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Paul Hillery 12-20-91
Paul Hillery, Ph.D.
Chemist

Asoke Mukherjee, Ph.D. 12-20-91
Pharmacologist

Richard A. Stein 12/20/91
Richard Stein, Ph.D.
Statistician

Enclosure
cc: Original NDA 19-645
HFD-007/Div. File
HFD-100/P.Berry
HFD-007/TPTaira
HFD-007/KMalek
HFD-007/PLove
HFD-007/PHillery
HFD-007/DBashaw
HFD-007/AMukherjee
HFD-007/RStein
HFD-007/DPease
HFD-007/LVaccari/12-18-91
HFD-340/BBarton
HFI-20/F.Peterson
HFC-130/J.Allen
HFD-8
HFD-240
HFD-83 (with draft labeling)
HFD-232 (with labeling)
R/D Init. by: CMoody 12-19-91
F/T by: dwp 12-20-91
Wang 2057P
APPROVAL

JPTaira 12/20/91

Conrad H. Chen Dec. 20, 1991

E.L. Barton for V. Hale 12/20/91

for P. Mathews 12/20/91