CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-499

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-499

Bayer Corporation
400 Morgan Lane
West Haven, Connecticut 06516-4175

OCT 0 6 1995

Attention: Carl E. Calcagni, R.Ph.
Vice President, Regulatory Affairs

Dear Mr. Calcagni:

Please refer to your July 15,1994 new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actron (ketoprofen) OTC 12.5mg oral tablets.

We refer to the approvable letter dated July 19, 1995 in which we requested revised labeling in draft mock-up form. We also acknowledge receipt of your amendment dated October 4, 1995.

This new drug application provides for a pain reliever/fever reducer to be used in the over the counter market.

We have completed the review of these applications including the submitted draft labeling 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 in the submissions dated October 4, 1995. Accordingly, the following components of your draft labeling: **Consumer Labeling Leaflet, 100 Caplet Carton/Bottle, 100 Tablet Carton/Bottle, 50 Caplet Carton/Bottle, 50 Tablet Carton/Bottle, 24 Caplet Carton/Bottle, 24 Tablet Carton/Bottle,** are approved. The approval is effective on the date of this letter.

The final printed labeling (FPL) for the above listed items must be identical to the draft labeling submitted on October 4, 1995. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit fifteen 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 NDA 20-499. Approval of this labeling by FDA is not required before it is used.

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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. 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:

Lissante LoBianco
Project Manager
301-443-4250

Sincerely yours,

Reviewing Team
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Pharmacologist

cc:
Original NDA 20-499
HFD-007/Div. files
HFD-007/CSO/D.Morgan
HFD-007/CFang/BHo/RStein/ACoulter/TTaira
HFD-160/RStevens
HFD-2/M.Lumpkin
HFA-100
DISTRICT OFFICE
HF-2/medwatch (with labeling)
HFD-80 (with labeling)
HFD-240/S.Sherman (with labeling)
HFD-613 (with labeling - Only for applications with labeling.)
HFD-735/DBarash (with labeling)
OFFICE FILE/Weintraub (with labeling)
HFI-80/FPeterson (with labeling)
HFD-8/PSavino (with labeling)
HFD-340/BBarton

drafted: /October 10, 1995/kp
r/d Initials: LLoBianco
final:

APPROVAL