

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-676**

PHARMACOLOGY REVIEW(S)

ORIGINAL

PILOT DRUG EVALUATION STAFF

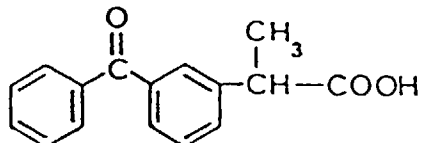
AUG 22 1994

PHARMACOLOGY AND TOXICOLOGY REVIEW

ORIGINAL SUBMISSION

NDA 20-499

DRUG: ACTRON® (ketoprofen 12.5 mg Tablet/Caplet)
BAY a 7790
CAS № 22071-15-4



2-(3-benzoylphenyl)-propionic acid
 $C_{16}H_{14}O_3$
Mol. Wt. 254.28

SPONSOR: Miles Inc.
Consumer Healthcare Products
1127 Myrtle Street
Elkhart, Indiana 46515

SUBMISSION DATE: July 15, 1994

REVIEWER: A. W. Coulter, Ph.D.

DATE REVIEW COMPLETED: August 19, 1994

DATE RECEIVED: July 19, 1994

DATE ASSIGNED: August 4, 1994

DRUG CATEGORY: NSAID

RELATED DRUGS/INDs/NDAs:

Ketoprofen

NDA 18-754 Orudis® 25, 50, 75 mg Rx, Wyeth-Ayerst
NDA 19-816 Ketoprofen 200 mg extended release Rx, Wyeth-Ayerst
NDA 20-429 Orudis® PR Tablets (Caplets) OTC, Whitehall-Robins

RECOMMENDATIONS:

There are no pharmacology/toxicology objections to the approval of NDA 20-499 for OTC distribution.

Almon W. Coulter, Ph.D.

Concur by peer leader: Yes No :

Lucy Jean, Ph.D.

Aug. 22, 1994

cc: NDA 20-499
HFD-7/Division File
 /ACoulter
 /CSO Morgan
HFD-502
HFD-345
F/T by ACoulter

**APPEARS THIS WAY
ON ORIGINAL**