

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-676**

CHEMISTRY REVIEW(S)

ORIGINAL

MAR 10 1995

PILOT DRUG EVALUATION STAFF HFD-007
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-499

REVIEW # 1

DATE REVIEWED: February 27, 1995

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
SUBMISSION	7 - 15 - 94	7 - 19 - 94	7 - 21 - 1994

NAME & ADDRESS OF APPLICANT:

Miles Inc.
Consumer Healthcare Products
Elkhart, Indiana 46515

DRUG PRODUCT NAME

Proprietary: Actron®
Established: Ketoprofen
Code Name/#: NA
Chem.Type/Ther.Class:

PHARMACOL. CATEGORY: NSAID

DOSAGE FORM: Tablet/caplet

STRENGTHS: 12.5 mg

ROUTE OF ADMINISTRATION: Oral

DISPENSED: _____ Rx X OTC

CONCLUSIONS & RECOMMENDATIONS:

From CMC standpoint, the submission is fileable.
Deficiencies cited in the review should be forwarded to the
sponsor for response.

cc:

Orig. NDA 20-499
HFD-007/Division File
HFD-007/MTheodorakis
HFD-007/CSO

Bart Ho, Review Chemist

filename: N20499C1.BBH

Peer Review Chemist

3/10/95