

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-842 / S-013

MEDICAL REVIEW

NDA 19-842
NDA 20-135
NDA 20-418
NDA 20-476

Labeling and Clinical Review of Labeling Revisions

Sponsor: McNeil Consumer Products

Products: Motrin (ibuprofen)

Materials Reviewed:

<u>SLR</u>	<u>Date submitted</u>	<u>Date received</u>	<u>Date completed</u>
19-842/S-013; Suspension	March 23, 1998	March 24, 1998	October 9, 2001
20-135/S-005; Chewable Tablets	October 6, 1998	October 7, 1998	October 9, 2001
20-135/S-005 (amend); Chewable Tablets	October 7, 1998	October 8, 1998	October 9, 2001
20-418/S-003; Caplets	October 6, 1998	October 7, 1998	October 9, 2001
20-418/S-003; Caplets	October 7, 1998	October 8, 1998	October 9, 2001
20-476/S-002; Oral Drops	October 6, 1998	October 7, 1998	October 9, 2001
20-476/S-002 (amend); Oral Drops	October 7, 1998	October 8, 1998	October 9, 2001

Background/Review Comments:

The above NDAs were approved as follows:

NDA 19-842	September 19, 1989
NDA 20-135:	November 16, 1994
NDA 20-418:	November 16, 1994
NDA 20-476:	May 25, 1995

On December 20, 1996, the Division sent a letter to all sponsors of NSAID labeling in regard to updating their labeling in accordance with "current divisional class labeling". These supplements reflect the sponsor's intent to comply with that request.

Although very similar to the divisional class labeling (aka "template" - attached), there are minor revisions. A comparison follows:

Sponsor Labeling	Reviewer Comments
DESCRIPTION	same as template
CLINICAL PHARMACOLOGY	appears to add appropriate
Pharmacodynamics	information
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<i>Absorption</i>	same as template
TABLE I Sponsor added appropriate numbers.	Acceptable
<i>Distribution</i>	Additions appear to be

WITHHOLD 2 PAGE(S)

Draft Labeling

Conclusions/Recommendations:

Although significant revisions, compared to the template dated December 1996, all revisions appear to only strengthen the labeling. An AP letter should be sent to the sponsor on all four supplements.

Lana L. Pauls, MPH
Review Standards Staff

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/s/

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10/10/01 10:27:20 AM
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2/4/02 10:34:36 AM
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