CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75661

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number:	75-661
Date of Submission:	January 19, 2001
Applicant's Name:	BASF Corporation
Established Name:	Ibuprofen Tablets and Caplets USP, 200 mg

Labeling Deficiencies:
General Comments:

Due to changes in the approved labels and labeling of the reference listed drug [Motrin IB® (ibuprofen) Tablets and Capsules; approved October 2, 2000] revise your labels and labeling accordingly. (Please refer to the enclosed labeling guidance for ibuprofen tablets, 200mg)

Please revise your labels and labeling, as instructed above, and submit in final print or draft if you prefer.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes-http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with the enclosed labeling guidance with all differences annotated and explained.

/S/

Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosed: A copy of the labeling guidance for ibuprofen tablets, 200mg

Drug Facts

Active ingredient (in each [insert dosage unit])	***Purposes***
Ibuprofen 200 mg	Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have

- stomach pain
- problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer

When using this product take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions[3]

- **do not take more than directed**
- adults and children 12 years and older:
  - take 1 [insert dosage unit] every 4 to 6 hours while symptoms persist
  - if pain or fever does not respond to 1 [insert dosage unit], 2 [insert dosage unit(s)] may be used
  - do not exceed 6 [insert dosage unit(s)] in 24 hours, unless directed by a doctor
  - the smallest effective dose should be used
- children under 12 years: ask a doctor

Other information

- optional - tamper evident statement
- store at 20-25° C (68-77° F). Avoid high humidity and excessive heat above 40° C (104° F).
- optional - see [end or side] panel for lot number and expiration date

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Inactive ingredients [list ingredients in alphabetical order]

Questions or comments? call toll free **1-800-XXX-XXXX**

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*NOTE: The **Drug Facts (continued)** title should appear wherever the labeling continues onto another panel of the package.*

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[3]The information for the two age groups can be presented in a table format in accord with 21 CFR 201.66(d)(9) with the "do not take more than directed" statement appearing above the top line of the table.

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-661

Date of Submission: June 30, 1999

Applicant's Name: BASF Corporation

Established Name: Ibuprofen Tablets USP, 200 mg

Labeling Deficiencies:

GENERAL COMMENTS

We acknowledge your comments regarding labeling revised to meet the requirements published in the Over-the-Counter Human Drugs; Labeling Requirements; Final Rule [Federal Register: March 17, 1999 (Volume 64, Number 51)]. However, the Drug Facts format has not been approved for the reference listed drug, Motrin IB, at this time. Revise your labels and labeling to be in accordance with the most recently approved labeling format of the reference listed drug, approved March 31, 1997.

Please revise your labels and labeling, as instructed above, and submit in draft print.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes-

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research