CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-139 / S-004

***Name*:** Ibuprofen Tablets USP, 200 mg

***Sponsor*:** LNK International, Inc.

***Approval Date*:** August 15, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-004

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-004

APPROVAL LETTER

ANDA 75-139/S-004
75-010/S-003

AUG 15 2002

Lnk International, Inc.
Attention: Pankaj S. Chudgar
60 Arkay Drive
Hauppauge, NY 11788

Dear Sir:

This is in reference to your supplemental new drug applications dated February 11, 2002 submitted pursuant to 21 CFR 314.70 (c) (Special Supplement – Changes Being Effected) regarding your abbreviated new drug applications for ibuprofen tablets USP, 200 mg.

These supplemental applications provide for revisions throughout the text of your container and carton labeling to be in accord with the most recently approved labeling for the reference listed drug (Motrin IB; NDA 19-012/S-024; approved October 2, 2000).

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

John L. Smith for 8-15-2002

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

cc:ANDA
Division File
Field Copy
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APPROVAL LETTER – MULTIPLE SUPPLEMENTS

Endorsements:
HFD-613/JBarlow 7/21/11

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-004

LABELING

FOLD

Drug Facts

Active ingredient (in each white tablet) — **Purpose**

Ibuprofen USP, 200 mg. ..... Fever Reducer / Pain Reliever

Uses for the temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps ■ For the reduction of fever

Ibuprofen 200

TABLETS

DO NOT USE IF THE IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

AUG 15 2002

Drug Facts (continued)

Warnings Do not combine this product with any other Ibuprofen containing product.

Do not use ■ if you have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives. Because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin ■ for pain for more than 10 days ■ for fever for more than 3 days ■ with aspirin or acetaminophen

LIFT HERE

outside

FOLD

Drug Facts (continued)

Ask a doctor before use if ■ you are being treated for a serious condition ■ you have any condition that requires you to take prescription drugs ■ you have had any problems or serious side effects from taking any non-prescription pain reliever

Stop use and ask a doctor if ■ you experience any symptoms which are unusual or seem unrelated to the condition for which you took Ibuprofen ■ pain or fever persists or gets worse ■ new symptoms occur ■ the painful area is red or swollen ■ more than mild heartburn, upset stomach or stomach pain occurs with use

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 SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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

AUG 15 2002

inside: left

FOLD

Drug Facts (continued)

Directions The smallest effective dose should be used. Take with food or milk if occasional or mild heartburn, upset stomach, or stomach pain occurs with use.

■ **adults:** take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor

■ **children:** do not give this product to children under 12 except under the advice and supervision of a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING** ■ store at controlled room temperature ■ avoid excessive heat 40°C (104°F)

Inactive ingredients cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polyethylene glycol, polyvinylpyrrolidone, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

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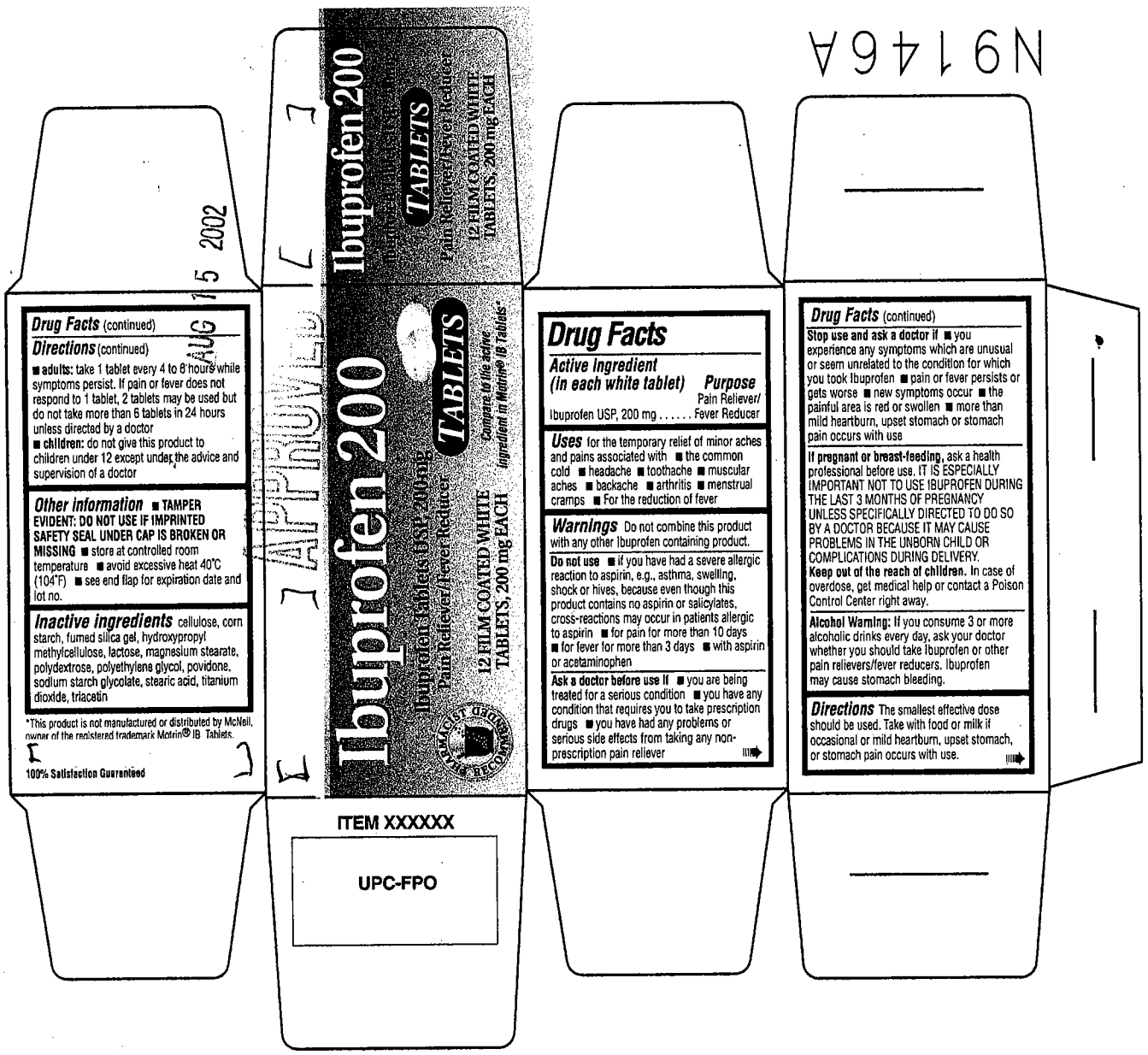
AUG 15 2002

inside: right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APPROVED
AUG 15 2002
Drug Facts (continued)
Directions (continued)
■ adults: take 1 tablet every 4 to 8 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor
■ children: do not give this product to children under 12 except under the advice and supervision of a doctor
Other information ■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING ■ store at controlled room temperature ■ avoid excessive heat 40°C (104°F) ■ see end flap for expiration date and lot no.
Inactive ingredients cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, titanium dioxide, triacetin
*This product is not manufactured or distributed by McNeil, owner of the registered trademark Motrin® IB Tablets.
100% Satisfaction Guaranteed
Ibuprofen 200
TABLETS
Pain Reliever/Fever Reducer
12 FILM COATED WHITE TABLETS, 200 mg EACH
Ibuprofen 200
TABLETS
Ibuprofen tablets USP, 200 mg
Pain Reliever/Fever Reducer
Compare to the active ingredient in Motrin® IB Tablets*
12 FILM COATED WHITE TABLETS, 200 mg EACH
PHARMACIST RECOMMENDED
ITEM XXXXXX
UPC-FPO
Drug Facts
Active Ingredient (in each white tablet) Purpose
Ibuprofen USP, 200 mg ..... Pain Reliever/ Fever Reducer
Uses for the temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps ■ For the reduction of fever
Warnings Do not combine this product with any other Ibuprofen containing product.
Do not use ■ if you have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin ■ for pain for more than 10 days ■ for fever for more than 3 days ■ with aspirin or acetaminophen
Ask a doctor before use if ■ you are being treated for a serious condition ■ you have any condition that requires you to take prescription drugs ■ you have had any problems or serious side effects from taking any non-prescription pain reliever
Drug Facts (continued)
Stop use and ask a doctor if ■ you experience any symptoms which are unusual or seem unrelated to the condition for which you took Ibuprofen ■ pain or fever persists or gets worse ■ new symptoms occur ■ the painful area is red or swollen ■ more than mild heartburn, upset stomach or stomach pain occurs with use
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 SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.
Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
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.
Directions The smallest effective dose should be used. Take with food or milk if occasional or mild heartburn, upset stomach, or stomach pain occurs with use.

▼ LIFT HERE ▼

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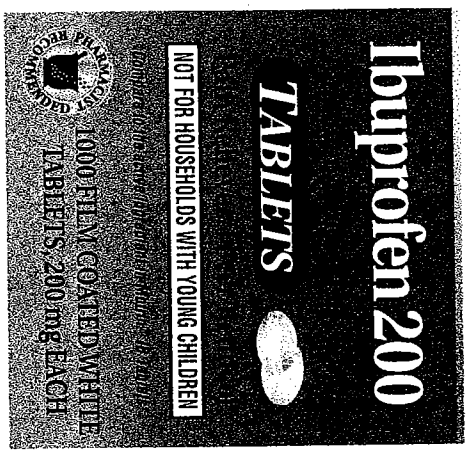

Drug Facts

Active ingredient (in each white tablet) **Purpose**

Ibuprofen USP, 200 mg ..... Pain Reliever/Fever Reducer

Uses for the temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps ■ For the reduction of fever

Warnings Do not combine this product with any other Ibuprofen containing product.

Do not use ■ if you have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin ■ for pain for more than 10 days ■ for fever for more than 3 days ■ with aspirin or acetaminophen

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- **adults:** take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor
- **children:** do not give this product to children under 12 except under the advice and supervision of a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING** ■ store at controlled room temperature ■ avoid excessive heat 40°C (104°F)

Inactive ingredients cellulose, corn starch, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

*This product is not manufactured or distributed by McNeil, owner of the registered trademark Motrin® IB Tablets.

Made in USA

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100% Satisfaction Guaranteed

UPC-FPO

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APPLICATION NUMBER:

ANDA 75-139 / S-004

ADMINISTRATIVE DOCUMENTS

JFG SPECIAL

CBE Labeling Supplement Routing Form

This form is to accompany the CBE (Changes Being Effected) Labeling Supplement(s). Upon completion, please return it to the OGD (Office of Generic Drugs) Document Room.

I. To be completed by the OGD Document Room using information from the applicant cover letter:

ANDA #	Supplement #	Doc Date
75-139	SL 004/A1	11 Feb. 2002

II. To be determined by the Labeling Team Leader:

Granted	Denied	Date
2/19/2002		

III. Comment:

IV. Signature:

(revised Jun 29, 2001)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-004

CORRESPONDENCE

L N K INTERNATIONAL, INC.

Over-The-Counter Pharmaceutical Manufacturer

60 Arkay Drive, Hauppauge, LI, NY 11788

ANDA 75-010 Ibuprofen USP 200mg Film Coated Brown Tablets
ANDA 75-139 Ibuprofen USP 200mg Film Coated White Tablets
Labeling Revision

February 11, 2002

Mr. J. Barlow
Food and Drug Administration
Office of Generic Drugs
CDER
8700 Standish Place
Metro Park North II
Rockville, MD 20855

NDA NO. 75-139 REF. NO. SL-004/AT
NDA SUPPL FOR Labeling Rev.

Supplement: Changes Being Effected
Labeling Change to Comply with OTC Requirements

ANDA [redacted] Ibuprofen USP, 200mg White Film Coated Tablets (RLD = Motrin)
ANDA 75-010; Ibuprofen USP, 200mg Brown Film Coated Tablets (RLD = Advil)

Dear Mr. Barlow:

This is a Special Supplement - Changes Being Effected. The effective date is May 16, 2002 based on the **OVER-THE-COUNTER HUMAN DRUGS; LABELING REQUIREMENTS; PARTIAL EXTENSION OF COMPLIANCE DATES; FR FDA 06/20/2000 F 65 FR 38191.** Our understanding is that this date is a shipment date and has no affect on product previously shipped with the old label and labeling. LNK is responding to a fax request dated January 24, 2002. The fax had provided a copy of approved label and labeling for the Reference Listed Drug (RLD), Motrin IB NDA 19-012/S-024. We were instructed to make necessary revisions and submit as a CBE labeling supplement.

LNK had submitted a supplement for a second color ***(Orange)*** in our approved Abbreviated New Drug Application, ANDA 75-139, **Ibuprofen, USP, 200mg White Tablets.** This supplement included a model label and labeling based on the requirements in 21 CFR 201.66 and the approved label and labeling of Motrin IB. Attached are copies of smallest and largest size model label and labeling that will be used in all label and labeling for the approved packaging sizes and in the third party product label and labeling that LNK manufactures and packages. LNK commits to submitting Final Printed Labels in our Annual Report.

LNK is certain that the information is sufficient for a comprehensive review of the supplemental request. If there is need for additional information, please call me at 631-543-3787.

CENTER FOR DRUG EVALUATION AND RESEARCH
FEB 12 2002

Sincerely,

Pankaj S. Chudgar
Vice President

PSC/dju
Enc.

Telephone: (631) 435-3500 - Facsimile: (631) 435-3542 - E-Mail: lnk01@ix.netcom.com