CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-139 / S-008

***Name*:** Ibuprofen Tablets USP, 200 mg (white)

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

***Approval Date*:** November 4, 2005

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-008

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APPLICATION NUMBER:

ANDA 75-139 / S-008

APPROVAL LETTER

ANDA 75-139/S-008(White Round and Capsule Shaped Tablets)
75-010/S-007(Brown Round and Capsule Shaped Tablets)

NOV 0 4 2005

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 September 22, 2005, submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications for Ibuprofen Tablets USP, 200 mg.

The supplemental applications submitted as "Supplement- Changes Being Effected in 30 Days" provide for:

> The change of manufacturing process of the drug substance, Ibuprofen. In the new process, ——— centrifuge is being replaced by the ——— centrifuge.

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,

Paul Schwartz for 11/3/05

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75139 and 75010
Division File
FIELD COPY

Endorsements:

HFD-617/A. Mueller, Ph.D. /Team Leader 11-3-05
HFD-617/S.Eng/P.M./ R 11/3/05

F/T by SE
V:\FIRMSAM\LNK\LTRS&REV\75139.s008.75010.s007.ap.doc

Supplement Approval

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-008

ADMINISTRATIVE DOCUMENTS

CBE Routing Form

This form is to accompany all CBE Supplements. Upon completion, return to the OGD Document Room.

I. To be completed by the OGD Document Room:

LETTER DATE: 9-22-05

APPLICATION: 75139 SUPPLEMENT(S): SCR-008 AI

Submitted as: **CBE-Zero** **CBE-30** **Labeling CBE**

II. To be completed by the Chemistry/Micro Division Staff:

A. This qualifies as:

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *
CBE-Zero / CBE-30	CBE-Zero / CBE-30	CBE-Zero / CBE-30
GK 10/17	10-19-05	Deals with Drug Substance Insp.

B. Does not qualify. This is Annual Reportable.

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *

C. Does not qualify. This is a Prior Approval Supplement.

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *

* Div/ Deputy Director signature needed only when: 1.) CBE is elevated to a PAS or 2.) PM/TL recommend different actions

III. Labeling CBE

Granted: _____ Denied: _____

Team Leader Signature: _____ Decision Date: _____

IV. Basis for Decision/Comments:

Δ manufact process of API

V. Project Manager Chemistry Team:

Prepare letter and notify applicant by telephone when CBE is denied because it is a Prior Approval Supplement. DATE: _____

Notify applicant by telephone that inappropriate CBE category used. DATE: _____

Request that applicant withdraw supplement, and submit the changes with the next Annual Report. DATE: _____ .

called firm to Δ to CBE-30

VI. Document Room: Record appropriate CBE code and file in archival submission.
Granted (GR); Doesn't qualify, inappropriate CBE category (DC); Doesn't qualify, it's AR (DA); Doesn't qualify, it's a PAS (DN)

FINAL DECISION: GK DATE: 11/2/05

CBE Zero ____ CBE 30 ✓ Prior Approval ____ Annual Report ____

Put to write approval letter

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-008

CORRESPONDENCE

L N K INTERNATIONAL, INC.

Over-The-Counter Pharmaceutical Manufacturer

60 Arkay Drive, Hauppauge, LI, NY 11788

September 22, 2005

Food and Drug Administration
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Metro Park North II
Room 150
7500 Standish Place
Rockville, MD 20855

NDA NO. 75/139 REF NO. SCR-008AI
NDA SUPPL. FOR MANUFACTURING CHG

Δ to CBE-30

S-008/CBE-30

Subject: Special Supplement Change Being Effected - Immediate
ANDA #75-139 Ibuprofen 200mg White Round and Capsule Shaped Tablets
ANDA # 75-010 Ibuprofen 200mg Brown Round and Capsule Shaped Tablets

Dear Sir:

In reference to our approved ANDA #75-139 (Ibuprofen 200mg White Round and Capsule Shaped Tablets) and ANDA #75-010 (Ibuprofen 200mg Brown Round and Capsule Shaped Tablets), LNK submits a Special upplement Changes Being Effected based on **Guidance for Industry 1999.** Changes to approved NDA or ANDA and a letter (Exhibit 1) from ———— the manufacturer and supplier of the drug substance Ibuprofen (alternate supplier).

————. has changed the manufacturing process of the active drug substance Ibuprofen. In the new process ———— centrifuge is being replaced by ———— centrifuge. Since ————. has notified the agency and informed them that the changes do not have any impact on the drug substance, we intend to make the change immediately on the new batches of drug substance, upon receiving from ————, with '———— centrifuge".

LNK requests the FDA to review the Letter of Authorization - Ibuprofen DMF # —— provided by ———— (Exhibit 2). LNK also commits to placing the first lot of drug product of each ANDA manufactured with the "new" drug substance on stability and will report the stability results in our Annual Report.

LNK is confident the information provided in this Supplement to our Approved ANDA is adequate to approve the change. If there are additional requirements or questions pertaining to this supplement, please contact me at (631) 543-3787.

Sincerely,

RECEIVED
SEP 2 3 2005
OGD/CDER

Pankaj S. Chudgar
Vice President

PSC/dju

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