CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-139 / S-007

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

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

***Approval Date*:** July 19, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-007

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Labeling Reviews	
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APPLICATION NUMBER:

ANDA 75-139 / S-007

APPROVAL LETTER

JUL 19 2004

ANDA 75-139/S-007
ANDA 75-010/S-006

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

Dear Sir:

This is in reference to your supplemental new drug applications dated February 27, 2004, submitted pursuant to 505 (j) of the Federal Food, Drug and Cosmetic Act, regarding your abbreviated new drug applications for Ibuprofen Tablets, 200 mg (75-010) (brown) and Ibuprofen Tablets USP, 200 mg (75-139) (white).

These supplemental applications, reclassified as "Changes Being Effected in 30 Days" provide for the following change:

Replacement of [redacted] with [redacted] during the manufacture of Ibuprofen (active pharmaceutical ingredient) by the [redacted].

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 Jr 7/19/04

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

cc: ANDA 75-010/S-006
75-139/S-007
Division File
Field Copy

Endorsements:

HFD-623/R. Bykadi, Ph.D./Chemistry Reviewer/ June 21, 2004 G. Bykadi 7-16-04
HFD-623/A.Mueller, Ph.D./ Team Leader/6/21/04 A. Mueller 7-16-04
HFD-617/S. Eng, PM/7/12/04 7/16/04

F/t by: ARD/7/15/04

V:\FIRMSAM\LNK\LTRS&REV\75010.S006.REV1.doc

Approvable - Minor

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-007

CHEMISTRY REVIEW

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Review of Supplement to an
Abbreviated New Drug Application

Ibuprofen Tablets, 200 mg

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1. CHEMISTRY REVIEW #1

2. ANDA # 75-010 and 75-139

3. NAME AND ADDRESS OF APPLICANT
LNK International, Inc.
Attention: Pankaj S. Chudgar
60 Arkay Drive
Hauppauge, LI, NY 11788

Tel: (631) 543-3787
Fax: (631) 543-2040

4. LEGAL BASIS FOR SUBMISSION
Section 505 (j), FFD & CA

5. SUPPLEMENT(s)
S-006 for ANDA 75-010 and
S-007 for ANDA 75-139

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME

75-010: Ibuprofen Tablets, USP, 200 mg Brown Tablets
75-139: Ibuprofen Tablets, USP, 200 mg White Tablets

8. SUPPLEMENT(s) PROVIDE(s) FOR: (For both ANDAs)

Replacement of ——— with ——— during the manufacture of Ibuprofen (active pharmaceutical ingredient) by the ———

9. AMENDMENTS AND OTHER DATES:

February 27, 2004 Supplement submission date for both ANDA's

10. PHARMACOLOGICAL CATEGORY
Analgesic, Antipyretic, and Anti-inflammatory

11. Rx or OTC
OTC

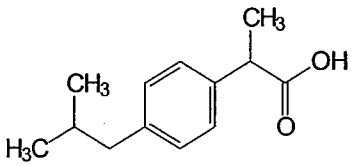
12. RELATED IND/NDA/DMF(s)
See #37

13. DOSAGE FORM Tablet

14. POTENCY 200 mg

15. CHEMICAL NAME AND STRUCTURE

Ibuprofen. Benzeneacetic acid, alpha-methyl-4-(2-methylpropyl), ±-. $C_{13}H_{18}O_2$. 206.29. 15687-21-1, 58560-75-1.
Anti-inflammatory.
(See USP 24, 856).



16. RECORDS AND REPORTS
N/A

17. COMMENTS: The firm did not send the completed FDA form 356h along with the supplement. The firm will be requested to send this form by fax.

18. CONCLUSIONS AND RECOMMENDATIONS
Approvable

19. REVIEWER:
Raj Bykadi

DATE COMPLETED:
June 21, 2004

cc: ANDA 75-010/S-006
75-139/S-007
Division File
Field Copy

Endorsements:
HFD-623/R. Bykadi, Ph.D., Chemistry Reviewer/June 21, 2004 R. Bykadi 7-16-04
HFD-623/A. Mueller, Ph.D., Team Leader/6/21/04 A. Mueller 7-16-04
HFD-617/S. Eng, Project Manage/7/12/04 S. Eng 7/16/04

F/T by:ard/7/15/04

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ON ORIGINAL

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of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #1

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-007

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:

SPECIAL

LETTER DATE: 2-27-04

APPLICATION: 75-139 SUPPLEMENT(S): SCF-007/AT

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

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

To Actions

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
Denied	3/12/04 Rosaria/R	

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:

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: _____

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: CBE 30 DATE: 3/12/04

CBE Zero Denied CBE 30 GR Prior Approval____ Annual Report____

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-007

CORRESPONDENCE

ANDA #75-139 Ibuprofen 200mg White Tablets
ANDA #75-010 Ibuprofen 200mg Brown Tablets

L N K INTERNATIONAL, INC.

Over-The-Counter Pharmaceutical Manufacturer

60 Arkay Drive, Hauppauge, LI, NY 11788

February 27, 2004

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. SCE-007
NDA SUPPL FOR Supplier addition

Subject: Special Supplement
Change being Effected - Immediate
ANDA #75-139 Ibuprofen 200mg White Tablets
ANDA #75-010 Ibuprofen 200mg Brown 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 Supplement 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 active drug substance, Ibuprofen. In the new process _____ is being replaced by _____. Since _____ has notified the agency and informed LNK that the change does not have an impact on the drug substance, we intend to make the change immediately on the new batches of drug substance received from _____ ; with _____.

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

RECEIVED
MAR - 1 2004
OGD/CDER

Sincerely,

Pankaj S. Chudgar
Vice President

PSC/dju
Enc.

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