CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-139 / S-001

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

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

***Approval Date*:** August 15, 2001

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APPLICATION NUMBER:

ANDA 75-139 / S-001

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Reviews / Information Included in this Review	
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Statistical Review(s)	
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Administrative Documents	X
Correspondence	X

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APPLICATION NUMBER:

ANDA 75-139 / S-001

APPROVAL LETTER

ANDA 75-139/S-001

AUG 15 2001

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

Dear Sir:

This is in reference to your supplemental new drug application dated April, 2001, submitted pursuant to section 505 (j) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen Tablets USP, 200 mg.

The supplemental application, submitted as "Changes Being Effected", provides for a change in the source of [redacted], in the manufacturing process for the [redacted], by the [redacted] manufacturer, [redacted].

We have completed the review of this supplemental application and it is 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 S. Lee for 8/10/01

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

CC: ANDA 75-139
Division Files
Field Copy

Endorsements:
HFD-625/U.S. Atwal, Ph.D./08/06/01 USAtwal 8/10/01
HFD-625/D. Gill, Ph.D./08/06/01 DSGill 8-10-01
HFD-617/R.Yu, Pharm. D./08/08/01 PSMarch for R.Y. 8/10/01
FT/njg/08/09/01
V:\FIRMSAM\LNK\LTRS&REV\7513901.RV1

SUPPLEMENT - APPROVABLE

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-001

CHEMISTRY REVIEW

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. **CHEMISTRY REVIEW** NO. 1 CBE-0

2. **ANDA #** 75-139/S-001

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

4. **LEGAL BASIS FOR SUBMISSION**
Approved ANDA

5. **SUPPLEMENT(s)** S-001

6. **PROPRIETARY NAME** N/A

7. **NONPROPRIETARY NAME**
Ibuprofen Tablets, USP

8. **SUPPLEMENT(s) PROVIDE(s) FOR:**
A change in the source of [redacted], in the manufacturing process for the [redacted], by the [redacted] manufacturer, [redacted].

9. **AMENDMENTS AND OTHER DATES:**
Date of Submission April 20, 2001

10. **PHARMACOLOGICAL CATEGORY**
Anti-inflammatory, Analgesic and Anti-pyretic

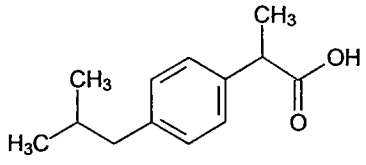
11. **Rx or OTC**
Rx

12. **RELATED IND/NDA/DMF(s)**
N/A

13. **DOSAGE FORM**
Tablet

14. **POTENCY**
200 mg

15. **CHEMICAL NAME AND STRUCTURE**
Ibuprofen. Benzeneacetic acid, α-methyl-4-(2-methylpropyl), (±)-. $C_{13}H_{18}O_2$. 206.29. 15687-21-1, 58560-75-1. Anti-inflammatory.



16. **RECORDS AND REPORTS** N/A

17. **COMMENTS**
See Review

18. **CONCLUSIONS AND RECOMMENDATIONS**
Approvable

19. **REVIEWER:**
U.S. Atwal, Ph.D.

DATE COMPLETED
08/06/01

CC: ANDA 75-139
Division Files
Field Copy

Endorsements:
HFD-625/U.S. Atwal, Ph.D./8/06/01 USAtwal 8/10/01
HFD-625/D. Gill, Ph.D./8/06/01 DSGill 8-10-01
HFD-617/R.Yu, Pharm. D./ RBrunelle for RY 8/10/01
FT/njg/8/09/01
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APPEARS THIS WAY
ON ORIGINAL

Redacted 1 page(s)

of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #1

37. **DMF CHECKLIST FOR ANDA #75-139/S-001**

Satisfactory

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
[redacted]	II/[redacted]	3	Adequate	03/01/01

Comment: Reviewed by R. Bykadi (no updates have been submitted since this review)

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:

(2) Type 1 DMF;
(3) Reviewed previously and no revision since last review;
(4) Sufficient information in application;
(5) Authority to reference not granted;
(6) DMF not available;
(7) Other (explain under"Comments").

Reviewer Signature

8/10/01
Date

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APPLICATION NUMBER:

ANDA 75-139 / S-001

ADMINISTRATIVE DOCUMENTS

CBE- ZERO (0) DAY SUPPLEMENT ROUTING FORM

This form is to accompany all CBE-Zero (0) Day supplements. Upon completion, return to the OGD Document Room.

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

DATE PROCESSED: 04-23-01
APPLICATION # : 75-139 SUPPLEMENT # : SCR-001/A1

II: **To be determined by Chemistry Division Staff:**

Date and Initial appropriate category.

Zero (0) Day CBEs:

Chemistry Div. Staff	Qualifies as CBE-0 (GR)	Does Not Qualify. This is a CBE-30 (DC)	Does not Qualify. This is an Annual Report (DA)	Does not Qualify. This is a Prior Approval Suppl. (DN)
Chem/Micro Project Manager(s)	P.M.P 5/8/01			
Micro and/or Labeling Team Leader (as needed)				
Chemistry Team Leader	DSGill 5-8-01			
Chemistry Div. Dir. Or Deputy Dir.*				

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

COMMENTS:

III. To Project Manager Chemistry Team 4 :

Prepare letter and notify applicant by telephone when CBE has been denied because it is a prior approval supplement.
DATE: _____

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

Request that applicant withdraw supplement when CBE qualifies for submission as an Annual Report DATE: _____

IV. **To Document Room:**

Record appropriate CBE Code CBE-0 (Grant)
File in archival submission

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-001

CORRESPONDENCE

L N K INTERNATIONAL, INC.

OVER-THE-COUNTER PHARMACEUTICAL MANUFACTURERS

60 ARKAY DRIVE, HAUPPAUGE, LI, NY 11788 • (516) 435-3500

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

April 20, 2001

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

NDA NO. 75139 REF. NO. SCE-001
NDA SUPPL FOR Manufacturing

SUBJECT: **Special Supplement**
Changes Being Effected – Immediate
ANDA # 75-139 (White) and ANDA # 75-010 (Brown)
For Ibuprofen 200mg 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 ———————— . ———— has changed the source of the ———————— ———————— in the manufacturing process for the ———————— . Since ———— has notified the agency and informed LNK that the change does not have an impact on the ———————— we intend to make the change immediately upon receipt of the first batch of ———————— with the changed source of ———— material.

LNK request that the FDA review the letter of Authorization ———— DMF # ——— provided by ———————— (Exhibit 2).

LNK also commits to placing the first lot of drug product of each ANDA manufactured with the "new" ———————— 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 ANDAs is adequate to approve the change. If there is additional requirements or question pertaining to this supplement please contact me by phone (631) 543-3787

Sincerely,

Pankaj S. Chudgar
Vice President

CENTER FOR DRUG
RECD
APR 23 2001
OGD
EVALUATION AND RESEARCH

4/24/01