CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-010 / S-002

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

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

***Approval Date*:** September 27, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010 / S-002

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Reviews / Information Included in this Review	
Approval Letter	X
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Labeling	
Labeling Reviews	
Medical Review(s)	
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Bioequivalence Review(s)	
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Administrative Documents	X
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010 / S-002

APPROVAL LETTER

ANDA 75-010/S-002

SEP 27 2001

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

Dear Sir:

This is in reference to your supplemental new drug application dated April 20, 2001 submitted pursuant to 505 (j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Ibuprofen Tablets USP, 200 mg (Brown).

This supplemental application, submitted as a "Changes Being Effected" provides for the following:

> Use of self-produced [redacted] in the manufacture of [redacted] instead of purchased [redacted] from an outside source.

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 Schwarz for 9/26/01

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

ANDA 75-010/S-002
Division File
DUP Jacket
Field Copy
HFD-92

Endorsements:

HFD-623/R. Bykadi, PHD, 9/17/01 R. Bykadi 9-24-01
HFD-623/A. Mueller, PHD, A. Mueller 9-24-01
HFD-617/T. Ames, PM, 9/20/01 for TA 9/25/01
F/T by: gp/9/24/01

CHEMISTRY REVIEW - APPROVABLE

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APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010 / S-002

CHEMISTRY REVIEW

OFFICE OF GENERIC DRUGS
ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

Ibuprofen Tablets USP, 200 mg

---

1. CHEMISTRY REVIEW #1

2. ANDA # 75-010/S-002

3. NAME AND ADDRESS OF APPLICANT

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

Tel: (516) 435-3500

4. LEGAL BASIS FOR SUBMISSION

Section 505 (j), FFD & CA

5. SUPPLEMENT(s) S-002 6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Ibuprofen Tablets, USP, 200 mg(brown)

8. SUPPLEMENT(s) PROVIDE(s) FOR:

S-002 Use of self-produced [redacted] by [redacted]

9. AMENDMENTS AND OTHER DATES:

April 20, 2001 Supplement submission

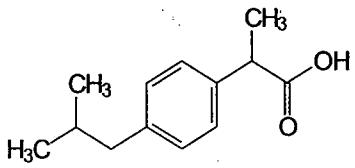
10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC OTC
Analgesic and Antipyretic

12. RELATED IND/NDA/DMF(s)
See below

13. DOSAGE FORM Tablet (Brown) 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. USP 23, p785.



16. RECORDS AND REPORTS
N/A

17. COMMENTS

L N K International submitted this supplement as CBE-0 supplement on April 20, 2001. The CBE-0 was not granted instead classified as CBE-30 (see CBE-0 supplement routing form,5-2-01)

18. CONCLUSIONS AND RECOMMENDATIONS
Approvable

19. REVIEWER: Raj Bykadi
DATE COMPLETED: September 14, 2001

cc: ANDA 75-010/S-002
Division File
Field Copy

Endorsements:

HFD-623/Raj Bykadi, PHD, /9/14/00 R. Bykadi 9-24-01
HFD-623/Albert Mueller, PHD, A. Mueller 9-24-01
F/t by: gp/9/24/01
File: \\CDS008\WP51F99\FIRMSAM\LNK\LTRS&REV\75010-S2rev1.doc

20. COMPONENTS AND COMPOSITION **N/A**

21. FACILITIES AND PERSONNEL **N/A**

22. SYNTHESIS **Satisfactory**

[redacted] and the all the data conforms to the approved specifications.

[redacted] has submitted an amendment to the DMF# [redacted] requesting the FDA for approval of equivalency.

DMF # [redacted] has been reviewed by R. Bykadi and it is satisfactory. A copy of a letter of authorization has been attached together with copies of appropriate data.

23. RAW MATERIAL CONTROLS **N/A**

24. OTHER FIRM(s) **N/A**

25. MANUFACTURING AND PROCESSING **N/A**

26. CONTAINER **N/A**

27. PACKAGING AND LABELING **N/A**

28. LABORATORY CONTROLS (IN-PROCESS AND FINISHED DOSAGE FORM) **N/A**

29. STABILITY Satisfactory
The firm commits to placing the first lot of the drug product of each ANDA manufactured with the "new" [redacted] on stability and will report the stability results in their annual reports.

30. CONTROL NUMBERS **N/A**

31. SAMPLES AND RESULTS **N/A**

32. LABELING **N/A**

33. ESTABLISHMENT INSPECTION **N/A**

34. BIOEQUIVALENCY STATUS **NA**

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:
N/A

36. ORDER OF REVIEW:
The application submission(s) covered by this review was taken in the date order of receipt Yes____X_____

If no, explain reason(s) below:

SPOT? Yes_____ No__X___

If yes, complete a SPOT form.

APPEARS THIS WAY
ON ORIGINAL

37. **DMF CHECKLIST FOR ANDA #75-010 Satisfactory**

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

Comments: Reviewed by R. Bykadi. No updates since last review. DMF is satisfactory

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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").

J. Bykadi 9-24-01

Reviewer Signature Date

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010 / S-002

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 # : 75-010 SUPPLEMENT # : SCR-002/A11

II: To be determined by Chemistry Division Staff:

Date and Initial appropriate category.

SPECIAL

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)			Appears to meet VI. D. 3. criteria. 4/26/01	
Micro and/or Labeling Team Leader (as needed)				
Chemistry Team Leader		4/27/2001		
Chemistry Div. Dir. Or Deputy Dir.*		5-1-01		

*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 1 :

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: 5/2/01

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

IV. **To Document Room:**

Record appropriate CBE Code GR
File in archival submission

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-010 / S-002

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. 75-010 REF. NO. SCR-002
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 EVALUATION AND RESEARCH
RECD
APR 23 2001
OGD