# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

*APPLICATION NUMBER:*

**ANDA 75-139 / S-006**

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

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

***Approval Date*:** February 4, 2003

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

# ANDA 75-139 / S-006

## CONTENTS

| Reviews / Information Included in this Review | |
|---|---|
| Approval Letter | X |
| Tentative Approval Letter | |
| Labeling | |
| Labeling Reviews | |
| Medical Review(s) | |
| Chemistry Reviews | X |
| Bioequivalence Review(s) | |
| Statistical Review(s) | |
| Microbiology Review | |
| Administrative Documents | |
| Correspondence | X |
| | |

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**ANDA 75-139 / S-006**

# APPROVAL LETTER

ANDA 75-139/S-006 (White tablets) ✓
ANDA 75-010/S-005 (Brown tablets)

FEB 4 03

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 May 1, 2002, 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) and Ibuprofen Tablets USP, 200 mg (white).

Reference is made to your amendments dated November 5, 2002 and January 17, 2003.

The supplemental applications, submitted as "Prior Approval Supplements" provide for the following changes:

75-010/S-005 and 75-139/S-006: Qualify Ibuprofen drug substance manufactured by ——— ——— as an alternate source

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 S. Lee 2/4/03

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-005
75-139/S-006
Division File
Field Copy

Endorsements:

HFD-623/R. Bykadi, Ph.D./January 30, 2003 S. Bykadi Feb 3, 2003
HFD-623/A.Mueller, Ph.D./ 2-3-03
HFD-617/C.Kiester, PM/2/3/03 2/4/03
F/t by: gp/2/3/03

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APPEARS THIS WAY
ON ORIGINAL

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

# ANDA 75-139 / S-006

# CHEMISTRY REVIEWS

**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**

---

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, NY 11788

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

4. LEGAL BASIS FOR SUBMISSION
Section 505 (j), FFD & CA – Prior approval supplements

5. SUPPLEMENT(s)
S-004 and S-005 for ANDA 75-010 and
S-005 and S-006 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 ANDA)

ANDA 75-010/S-004 and ANDA 75-139/S-005:

Qualify Ibuprofen drug substance manufactured by _____ _____ as an alternate supplier

ANDA 75-010/S-005 and ANDA 75-139/S-006:

Qualify Ibuprofen drug substance manufactured by _____ as an alternate source

9. AMENDMENTS AND OTHER DATES:

April 22, 2002 - Supplement submission date for ANDA 75-010/S-004 and 75-139-005

May 1, 2002 - Supplement submission date for ANDA 75-010/S-005 and 75-139/S-006

10. PHARMACOLOGICAL CATEGORY
Analgesic and Antipyretic

11. Rx or OTC
OTC

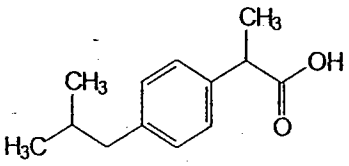
12. RELATED IND/NDA/DMF(s)
See #37

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
See below

18. CONCLUSIONS AND RECOMMENDATIONS
Not Approvable

19. REVIEWER:
Raj Bykadi

DATE COMPLETED:
September 19, 2002

cc: ANDA 75-010/S-004 and S-005
75-139/S-005 and S-006
Division File
Field Copy

Endorsements:
HFD-623/R. Bykadi, Ph.D./September 19, 2002 R. Bykadi Sept 27, 02
HFD-623/A. Mueller, Ph.D./ A Mueller 9-27-02
HFD-617/C. Kiester, PM/ C Kiester 10/1/02
File:
F/T by:

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CHEMISTRY REVIEW #1

**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**

---

1. CHEMISTRY REVIEW #2

2. ANDA # 75-010 and 75-139

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

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

4. LEGAL BASIS FOR SUBMISSION
Section 505 (j), FFD & CA – Prior approval supplements

5. SUPPLEMENT(s)
S-004 and S-005 for ANDA 75-010 and
S-005 and S-006 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 ANDA)

ANDA 75-010/S-004 and ANDA 75-139/S-005:

Qualify Ibuprofen drug substance manufactured by [redacted] as an alternate supplier

ANDA 75-010/S-005 and ANDA 75-139/S-006:

Qualify Ibuprofen drug substance manufactured by [redacted] as an alternate source

9. AMENDMENTS AND OTHER DATES:

April 22, 2002 - Supplement submission date for ANDA 75-010/S-004 and 75-139-005

May 1, 2002 - Supplement submission date for ANDA 75-010/S-005 and 75-139/S-006

**November 5, 2002- Amendments to supplements 75-139/S-006 and 75-010/S-005 only**

10. PHARMACOLOGICAL CATEGORY
Analgesic and Antipyretic

11. Rx or OTC
OTC

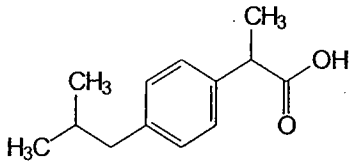
12. RELATED IND/NDA/DMF(s)
See #37

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

**In this amendment, the firm responded to the deficiencies concerning only qualification of —— Ibuprofen drug substance. The firm stated that the deficiencies regarding ———————— will be separately addressed at a later date. The firm fill be asked to either withdraw the ——— reference in the supplements or respond to the deficiency letter. See comments in bold letters.**

18. CONCLUSIONS AND RECOMMENDATIONS

Not Approvable

19. REVIEWER: Raj Bykadi

DATE COMPLETED: November 22, 2002

cc: ANDA 75-010/S-004 and S-005
75-139/S-005 and S-006
Division File
Field Copy

Endorsements:
HFD-623/R. Bykadi, Ph.D./November 22, 2002 R. Bykadi Dec 9, 2002
HFD-623/A. Mueller, Ph.D./ A. Mueller 12-9-02
HFD-617/C. Kiester, PM/ C. Kiester 12/6/02
File:
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CHEMISTRY REVIEW #2

**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***

---

1. CHEMISTRY REVIEW #3

2. ANDA # 75-010 and 75-139

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

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

4. LEGAL BASIS FOR SUBMISSION
Section 505 (j), FFD & CA – Prior approval supplements

5. SUPPLEMENT(s)
S-005 for ANDA 75-010 and
S-006 for ANDA 75-139

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME

75-010: Ibuprofen Tablets, USP, 200 mg Brown Tablets (RLD – Motrin)
75-139: Ibuprofen Tablets, USP, 200 mg White Tablets (RLD – Advil)

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

ANDA 75-010/S-005 and ANDA 75-139/S-006:

Qualify Ibuprofen drug substance manufactured by ——————— as an alternate source

9. AMENDMENTS AND OTHER DATES:

| | |
|---|---|
| April 22, 2002 - | Supplement submission date for ANDA 75-010/S-004 and 75-139-005 |
| May 1, 2002 - | Supplement submission date for ANDA 75-010/S-005 and 75-139/S-006 |
| November 5, 2002- | Amendments to supplements 75-139/S-006 and 75-010/S-005 only |
| **January 17, 2003** | **Amendments to supplements 75-139/S-006 and 75-010/S-005 only** |

10. PHARMACOLOGICAL CATEGORY
Analgesic and Antipyretic

11. Rx or OTC
OTC

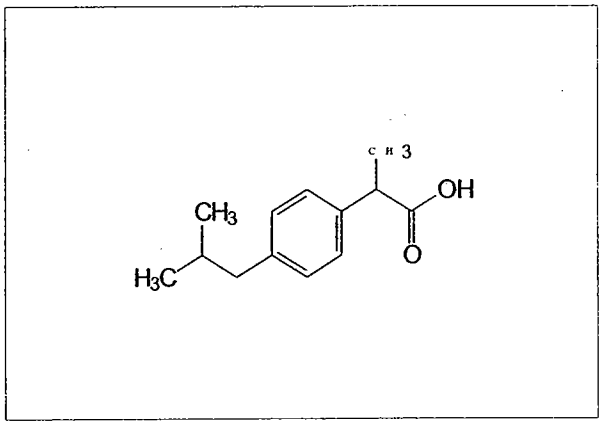
12. RELATED IND/NDA/DMF(s)
See #37

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 submitted its response for qualifying —— drug substance only. The firm stated that it would require additional time to respond to deficiencies pertaining to ——— drug substance (see review #1).

18. CONCLUSIONS AND RECOMMENDATIONS
Approvable (—— drug substance only)

19. REVIEWER: Raj Bykadi
DATE COMPLETED: January 28, 2003

cc: ANDA 75-010/S-005
ANDA 75-139/S-006
Division File
Field Copy

Endorsements:
HFD-623/R. Bykadi, Ph.D./January 30, 2003 G. Bykadi · Feb 3, 2005
HFD-623/A. Mueller, Ph.D./1/30/03 A. Mueller 2-3-03
HFD-617/C. Kiester, PM/2/3/03
File:
F/T by: gp/2/3/03

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CHEMISTRY REVIEW #3

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

# ANDA 75-139 / S-006

# CORRESPONDENCE

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

# L N K INTERNATIONAL, INC.

*Over-The-Counter Pharmaceutical Manufacturer*

**60 Arkay Drive, Hauppauge, LI, NY 11788**

May 1, 2002

Office of Generic Drugs
CDER, FDA
8700 Standish Place
Metro Park North II
Rockville, MD 20855

NDA NO. 75-139 REF NO. SLC-006
NDA SUPPL FOR Supplier

Supplement: Add Alternate Source - Ibuprofen
**ANDA 75-139; Ibuprofen USP, 200 mg White Tablets**
**Bioequivalence Data included**

Dear Sir:

LNK request a supplement for an alternate source (——————— for the drug substance, IBUPROFEN, in our approved Abbreviated New Drug Applications, ANDA 75-139 (RLD = Motrin) and ANDA 75-010 (RLD = Advil; BE study 159-01-11013/14), **Ibuprofen, USP, 200mg**. Our current source for drug substance is ———, DMF No. ——. The new source —— DMF is —. This supplement provides:

1. Component change information
2. DMF Authorization Letter
3. Executed test batch
4. Proposed production batch
5. Stability information
6. Comparative dissolution profile
7. In-Vivo Bioequivalency Waiver request

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.

Sincerely,

Pankaj S. Chudgar
Vice President

Enc.

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MAY 0 2 2002
OGD / CDER

O:\IBUPROFN\A-suppSource 5-18 ——

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

ANDA 75-139/ S-005 and S-006 (White tablets)
ANDA 75-010/S-004 and S-005 (Brown tablets)

OCT - 3 2002

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 April 22 and May 1, 2002, 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) and Ibuprofen Tablets USP, 200 mg (white).

These supplemental applications, submitted as "Prior Approval Supplements" provide for the following changes:

75-010/S-004 and 75-139/S-005:
Qualify Ibuprofen drug substance manufactured by ——————— as an alternate source.

75-010/S-005 and 75-139/S-006:
Qualify Ibuprofen drug substance manufactured by ——————— as an alternate source.

The supplemental applications are deficient and therefore, not approvable under section 505 of the act for the following reasons:

Deficiencies:

1.

2.

3.

4.

5.

6.

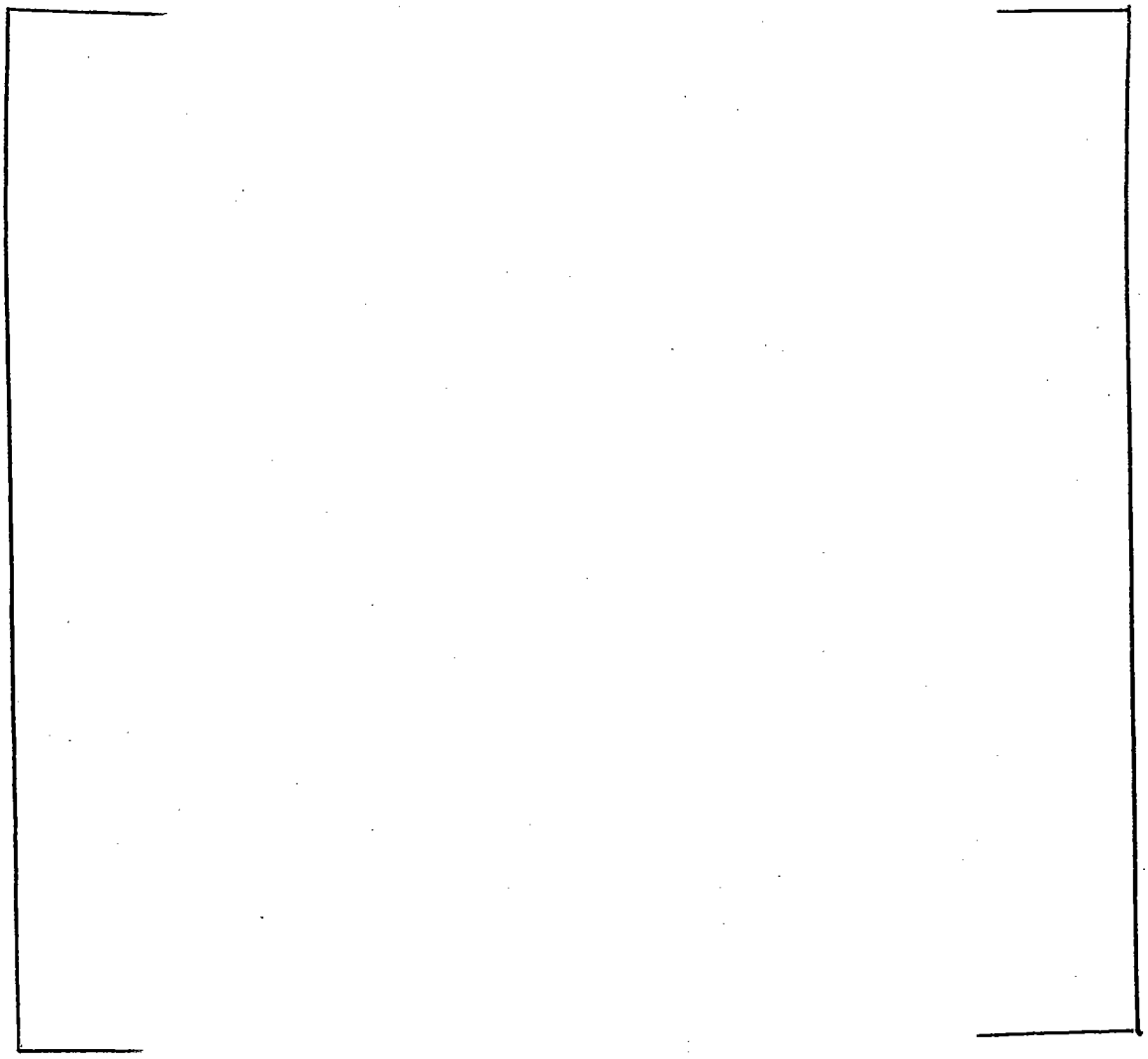
7.

8.

9.

10.

11.



Other Comment:

1. The firms referenced in your ANDA relative to the manufacturing and testing of the product must be in compliance with cGMP's at the time of approval. We have requested an evaluation from the Division of Manufacturing and Product Quality.

The file on these supplemental applications is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw this supplemental application. Your amendment should respond to all the deficiencies listed. Partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have

been addressed. The response to this letter will be considered as a MINOR amendment and should be so designated in your cover letter. If you have substantial disagreement with our reasons for not approving this supplemental application, you may request an opportunity for a hearing.

Sincerely yours,

10-2-02

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

APPEARS THIS WAY
ON ORIGINAL

cc: ANDA 75-010/S-004 and S-005
75-139/S-005 and S-006
Division File
Field Copy

Endorsements:

HFD-623/R. Bykadi, Ph.D./September 19, 2002 R. Bykadi October 2, 2002
HFD-623/A.Mueller, Ph.D./9/27/02 10-2-02
HFD-617/C.Kiester, PM/10/2/02
F/t by: gp/10/2/02
F/T by: \\CDS013\OGDS11\FIRMSAM\LNK\LTRS&REV\75010S4rev1.doc

APPEARS THIS WAY
ON ORIGINAL

ANDA 75-139 Ibuprofen USP 200 mg Film Coated Tablets
ANDA 75-010 Ibuprofen USP 200 mg Film Coated Tablets

# L N K INTERNATIONAL, INC.

OVER-THE-COUNTER PHARMACEUTICAL MANUFACTURERS

60 ARKAY DRIVE, HAUPPAUGE, LI, NY 11788 • (631) 435-3500

ANDA 75-139/S-006 —— source (White tablets)
ANDA 75-010/S-005 —— source (Brown tablets)

November 5, 2002

Dr Rashmikant Patel
Director, Chemistry I
Office of Generic Drugs
CDER, FDA
8700 Standish Place
Metro Park North II
Rockville, MD 20855

SCC005 AM
SUPPL AMENDMENT
SCC006/AM

Amendment to Supplement: Add Alternate Source – —— Ibuprofen
**ANDA 75-139/S-006; Ibuprofen USP, 200 mg Tablets**
**ANDA 75-010/S-005; Ibuprofen USP, 200 mg Tablets**

Dear Dr. Patel:

This amendment is in response to the deficiency letter dated October 3, 2002 for a supplement, dated May 1, 2002, to add an alternate supplier, ———— for the drug substance Ibuprofen. LNK had submitted two separate supplements to qualify alternate suppliers of the Active Pharmaceutical Ingredient (API) to both of our ANDA for Over-the-Counter Ibuprofen. Although, the supplements may appear the same, because the sources are different and the managements of the API manufacturers have their own ways of complying with our requests, we would like to preserve individuality of the supplements. This amendment will respond to all the deficiencies for the Ibuprofen source from ——. The other supplier,————————, had additional deficiencies and informed LNK that it will require more time to provide the information.

Deficiencies

[redacted]

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OGD / CDER

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11/5/2002 LNK LETTER

Other comments:

**1. The firms referenced in you ANDA relative to the manufacturing and testing of the product must be in compliance with cGMP's at the time of approval. We have requested an evaluation from the Division of Manufacturing and Product Quality.**

LNK acknowledges the requirement for cGMP compliance for the manufacturer —— and testing laboratory —— for Ibuprofen. As per information f rom these two firms, they are in compliance with all the cGMP requirements. We have notified these two companies of your requirements.

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.

Sincerely,

Pankaj S. Chudgar
Vice President

PSC/dju
Enc.

ANDA 75-139/ S-005 and S-006 (White tablets)
ANDA 75-010/S-004 and S-005 (Brown tablets)

JAN 10 2003

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 April 22 and May 1, 2002, 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) and Ibuprofen Tablets USP, 200 mg (white).

Reference is made to your amendment dated November 5, 2002.

These supplemental applications, submitted as "Prior Approval Supplements" provide for the following changes:

75-010/S-004 and 75-139/S-005:
Qualify Ibuprofen drug substance manufactured by ——————— as an alternate source.

75-010/S-005 and 75-139/S-006:
Qualify Ibuprofen drug substance manufactured by ——————— as an alternate source.

The supplemental applications are deficient and therefore, not approvable under section 505 of the act for the following reasons:

Deficiencies:

We note similarity factors (f2) on dissolution in your original submission (Exhibit 5). Please provide the calculations to show how you obtained these reported values and graphical representations of dissolution curves.

Additionally, you have not responded to the deficiencies concerning API supplied by ——————— (75-010/S-004 and 75-139/S-005). Please indicate whether you would like to withdraw these applications or indicate when you would respond to the deficiencies pertaining to——— API.

The file on these supplemental applications is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw this supplemental application. Your amendment should respond to all the deficiencies listed. Partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this letter will be considered as a MINOR amendment and should be so designated in your cover letter. If you have substantial disagreement with our reasons for not approving this supplemental application, you may request an opportunity for a hearing.

Sincerely yours,

1-9-03

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

APPEARS THIS WAY
ON ORIGINAL

cc: ANDA 75-010/S-004 and S-005
75-139/S-005 and S-006
Division File
Field Copy

Endorsements:

HFD-623/R. Bykadi, Ph.D./November 22, 2002 12/6/02 S. Bykadi, Dec 27, 200.
HFD-623/A.Mueller, Ph.D./12/9/02 1-9-03
HFD-617/C.Kiester, PM/12/26/02
F/t by: gp/12/27/02

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APPEARS THIS WAY
ON ORIGINAL

# L N K INTERNATIONAL, INC.

*Over-The-Counter Pharmaceutical Manufacturer*

**60 Arkay Drive, Hauppauge, LI, NY 11788**

ANDA 75-139/S-006 —— source (White tablets)
ANDA 75-010/S-005 —— source (Brown tablets)

January 17, 2003

Dr Rashmikant Patel
Director, Chemistry I
Office of Generic Drugs
CDER, FDA
8700 Standish Place
Metro Park North II
Rockville, MD 20855

SUPPL AMENDMENT
SCC006/AM

**MINOR AMENDMENT** to Supplement:
Add Alternate Source - Ibuprofen
**ANDA 75-139/S-006; Ibuprofen USP, 200 mg Tablets (RLD – Motrin)**
**ANDA 75-010/S-005; Ibuprofen USP, 200 mg Tablets (RLD – Advil)**

Dear Dr. Patel,

This amendment is in response to the deficiency letter dated January 10, 2003 October 3, 2002 for a supplement, dated May 1, 2002 and amended October 3, 2002, to add an alternate supplier, ————, for the drug substance Ibuprofen. LNK had submitted **two separate supplements to qualify alternate suppliers of the Active Pharmaceutical Ingredient (API)** to both of our ANDAs for Over-the-Counter Ibuprofen. Although, the supplements may appear the same, because the sources are different and the managements of the API manufacturers have their own ways of complying with our requests, we would like to preserve individuality of the supplements.

This amendment will respond to all the deficiencies for the Ibuprofen source from ——. The other supplier, ———— had additional deficiencies and informed LNK that it will require more time to provide the information. In fact, —— has altered their process since they supplied LNK with raw materials that were used in the exhibit batch. They did not tell us about the changes until after we submitted the supplement. LNK is trying to determine if the API has changed significantly enough to require manufacture of another exhibit batch. We ———— need to have an alternate supplier and we submitted two in hope of getting at least one of them approved. LNK still wishes to have both suppliers approved and we will be amending ANDA 75-139/S-005 —— and 75-010/S-004 —— as soon as ——— can satisfactorily explain whether the changes that they made would require another batch of finished product.

Deficiencies

**1. We note similarity factors (f2) on dissolution in your original submission (Exhibit 5). Please provide the calculations to show how you obtained these reported values and graphical representations of dissolution curves.**

LNK provided dissolution data and based the calculation of similarity factor on the guidance **DISSOLUTION TESTING OF IMMEDIATE RELEASE SOLID ORAL DOSAGE FORMS CDER 05/10/96.** We have reviewed our calculations and we have determined that we made an error in one of the calculations. LNK provides the calculations (Exhibit 1) and graphical representation of the dissolution curves (Exhibit 2).

RECEIVED
JAN 21 2003
OGD/CDER

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

LNK provided profile dissolution data and based the calculations of similarity factor ($f_2$) on the guidance "Dissolution Testing of Immediate Release Solid Oral Dosage Forms" CDER 05/10/96. However we found an error in the calculation of Ibuprofen 200 mg White Round Tablets imprint 44-352, Lot# P26702 (proposed new active ingredient Ibuprofen USP Supplied by ————————) and Ibuprofen White Round Tablets, Imprint 44-352, Lot# P27132 (current formulation) **ANDA 75-139**. In the similarity factor ($f_2$) calculation, the analyst instead of squaring the dissolution average difference of each time interval and adding the squared difference, the analyst added each time interval difference and then squared the sum of the difference. We have corrected the similarity factor and the new corrected similarity factor is 86.5% instead of 81.5%. We have corrected the calculation in the dissolution profile report. LNK provides the calculations and graphical representation of the dissolution curves (Exhibit 1)

**2. Additionally, you have not responded to the deficiencies concerning API supplied by ———— ———— (75-010/S-004 and 75-139/S005). Please indicate whether you would like to withdraw these applications or indicate when you would respond to the deficiencies pertaining to ———— API.**

LNK is responding to the ———— deficiencies under separate cover. We are requesting an extension for our reply. We are still waiting for information from ————about the changes that they made to their synthesis of Ibuprofen. We will withdraw the supplemental application (75-010/S-004 and 75-139/S005), if the changes were significant and require the production of another batch of finished product using ———— current raw material. We are just as disappointed and concerned about the delay as you seem to be.

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.

Sincerely,

Pankaj S. Chudgar
Vice President

PSC/dju
Enc.