CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-139 / S-005

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

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

***Approval Date*:** August 5, 2003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-005

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-005

APPROVAL LETTER

AUG - 5 2003

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

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 April 22, 2002 submitted pursuant to 505 (j) of the Federal Food, Drug and Cosmetic Act, regarding your abbreviated new drug applications for Ibuprofen Tablets USP, 200 mg (brown) and Ibuprofen Tablets USP, 200 mg (white).

Reference is also made to your amendment dated May 16, 2003.

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

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

We have completed the review of the 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 Shoaf Jr 8/1/03

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-004 and
75-139/S-005
Division File
Field Copy

Endorsements:

HFD-623/R. Bykadi, Ph.D./Review Chemist/July 23, 2003 R. Bykadi 8-4-03
HFD-623/A.Mueller, Ph.D./Team Leader/ A. Mueller 8-4-03
HFD-617/C.Kiester, PM/ C Kiester 8/4/03

F/T by:

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APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-005

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

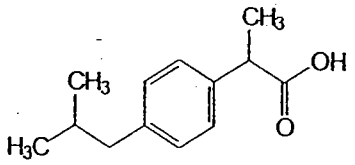
12. RELATED IND/NDA/DMF(s)
See #37

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 Supplements to
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 for ANDA 75-010
S-005 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

9. AMENDMENTS AND OTHER DATES:

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

May 16, 2003 - Amendment to the supplemental application

(Note the firm submitted an amendment for ANDA 75-010/S-005 and 75-139/S-006 to qualify Ibuprofen DS form ——— on May 1, 2003 as sister applications)

10. PHARMACOLOGICAL CATEGORY
Analgesic and Antipyretic

11. Rx or OTC
OTC

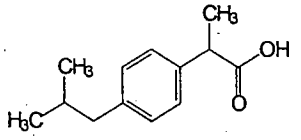
12. RELATED IND/NDA/DMF(s)
See #37

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
Approvable

19. REVIEWER:
Raj Bykadi

DATE COMPLETED:
July 23, 2003

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

Endorsements:
HFD-623/R. Bykadi, Ph.D./Review Chemist/ by Bykadi 7-30-03
HFD-623/A. Mueller, Ph.D./Team Leader/ 7-30-03
HFD-617/C. Kiester, PM/ 7/31/03
File:
F/T by:

V:\FIRMSAM\LNK\LTRS&REV\75010S4&75139S5R2.doc

APPEARS THIS WAY
ON ORIGINAL

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information from

CHEMISTRY REVIEW #2

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-005

BIOEQUIVALENCE REVIEW

Ibuprofen Tablets, USP
200 mg, White, round shape tablet
and capsule shape tablet
ANDA #75-139/S-005
Reviewer: Kuldeep R. Dhariwal
File name: V:\Firmsam\LNK\Ltrs&rev\75139S0402.doc

LNK International
60 Arkay Drive
Hauppauge, LI, NY 11788
Submission Date:
April 22, 2002

Review of a Supplement

LNK has two approved ANDAs for ibuprofen tablets:
#75010: 200 mg, brown color, round and capsule shaped tablets
#75139: 200 mg, white color, round and capsule shaped tablets
The firm has submitted supplements for a second source ( ) of the drug substance, ibuprofen in these approved ANDAs. The current source of the drug substance is .

This supplement is for white color, round and capsule shaped tablets (ANDA #75139). The supplement was submitted on April 22, 2002 and was assigned to this reviewer on October 24, 2002. The firm has submitted dissolution data and is requesting a waiver of *in vivo* bioequivalency requirements for an additional source of the drug substance.

Formulation:

The firm is not proposing any changes in the formulation of the tablets.

Dissolution:

Method: USP 25
Apparatus: 2 (paddle) at 50 rpm
Medium: Phosphate buffer, pH 7.2
Volume: 900 mL
Specifications: NLT 80% (Q) in 60 minutes.

Mean Dissolution Data

Test (current source of drug substance)				Test: (new source of drug substance)		
Lot No.: P27132, round tablets				Lot No.: P23134, round tablets		
Strength: 200 mg				Strength: 200 mg		
No. of Units: 12				No. of Units: 12		
Time(min)	Mean	Range	%CV	Mean	Range	%CV
15	99		1.3	99		1.8
30	101		1.2	100		1.5
45	97		0.6	97		1.2
60	97		1.2	97		1.2

Comments:

1. The firm has submitted comparative dissolution data on white round tablets manufactured using drug substance from ——— and ——————————— .
2. The dissolution testing was conducted using USP 25 method. The test products meet the specifications. The F_2 test is irrelevant as the products dissolve more than 95% in 15 minutes.
3. The firm markets round as well as capsule shaped tablets. However, the dissolution data were submitted on round shape tablets only. The formulation including that of the coating is same for round and capsule shaped tablets, the only difference is in the shape of the tablet. Since this supplement is for an additional source of the drug substance, there is no need to ask for additional dissolution data on capsule shaped white tablets as per Office of Generic Drugs' Policy and Procedure Guide #22-90. The white capsule shaped tablets can be waived under the principles of this guide.
4. This ANDA (#75-139) was originally approved based on the bio-studies conducted on brown round shape tablets (ANDA #75-010). The firm has separately submitted supplement for an additional source of drug substance for brown tablets. The waiver of *in vivo* bioequivalence study requirements for an additional source of drug substance in this ANDA is based on the similar waiver submitted for brown tablets (ANDA#75-010).

Recommendation:

The waiver of *in vivo* bioequivalence study requirements for an additional source of drug substance ——— is granted for white ibuprofen 200 mg tablets. However, this waiver is based on the similar waiver submitted for ibuprofen brown tablets (ANDA#75-010).

Dhariwal 10/31/02

Kuldeep R. Dhariwal, Ph.D.
Review Branch II
Division of Bioequivalence

RD INITIALED S. NERURKAR
FT INITIALED S. NERURKAR _____ Date 11/5/2002

for Concur: _____ Date 11-14-02

Dale P. Conner, Pharm. D.
Director
Division of Bioequivalence

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA:75-139/S-005 APPLICANT: LNK International

DRUG PRODUCT: Ibuprofen Tablets, USP
200 mg, white color

The Division of Bioequivalence has completed its review and has no further questions at this time.

The dissolution testing will need to be incorporated into your stability and quality control programs as specified in USP 25.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA 75-139/S-005
ANDA DUPLICATE
DIVISION FILE
FIELD COPY
DRUG FILE

Endorsements: (Draft and Final with Dates)
HFD-655/Dhariwal 10/31/02
HFD-655/Nerurkar
HFD-617/Nwaba
HFD-650/Dale Conner GJPS 11-14-02 11/5/02

BIOEQUIVALENCY - ACCEPTABLE Submission Date: 4/22/02

1. **STUDY AMENDMENT** (STA) Strengths: 200 mg
Outcome: AC

Outcome Decisions:

AC - Acceptable

APPEARS THIS WAY
ON ORIGINAL

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA # : 75-139/S-005 SPONSOR : LNK International

DRUG AND DOSAGE FORM : Ibuprofen Tablets, USP

STRENGTH(S) : 200 mg, white color

TYPES OF STUDIES : N/A

CLINICAL STUDY SITE(S) : N/A

ANALYTICAL SITE(S) : N/A

STUDY SUMMARY : The waiver of *in vivo* bioequivalence study requirements for an additional source of drug substance ——— is granted for white ibuprofen 200 mg tablets. However, this waiver is based on the similar waiver submitted for ibuprofen brown tablets (ANDA#75-010).

DISSOLUTION : Acceptable as per USP 25.

DSI INSPECTION STATUS

Inspection needed: NO	Inspection status:	Inspection results:
First Generic __No__ New facility _____ For cause _____ Other _____	Inspection requested: (date) Inspection completed: (date)	

PRIMARY REVIEWER : Kuldeep R. Dhariwal, Ph.D. BRANCH : II

INITIAL : KRD DATE : 10/31/02

TEAM LEADER : S. Nerurkar, Ph.D. BRANCH : II

INITIAL : SN DATE : 11/5/2002

DIRECTOR, DIVISION OF BIOEQUIVALENCE : DALE P. CONNER, Pharm. D.

INITIAL : GPG DATE : 11-14-02

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-005

CORRESPONDENCE

L N K INTERNATIONAL, INC.

Over-The-Counter Pharmaceutical Manufacturer

60 Arkay Drive, Hauppauge, LI, NY 11788

April 22, 2002

NDA NO. 75-139 REF. NO. SCC. 005

NDA SUPPL FOR Supplier Add

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

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

Dear Sir,

LNK request a supplement for a second source [redacted] 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 [redacted] DMF No. [redacted] The new source [redacted] DMF is [redacted] 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

RECEIVED
APR 23 2002
OGD / CDER

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.

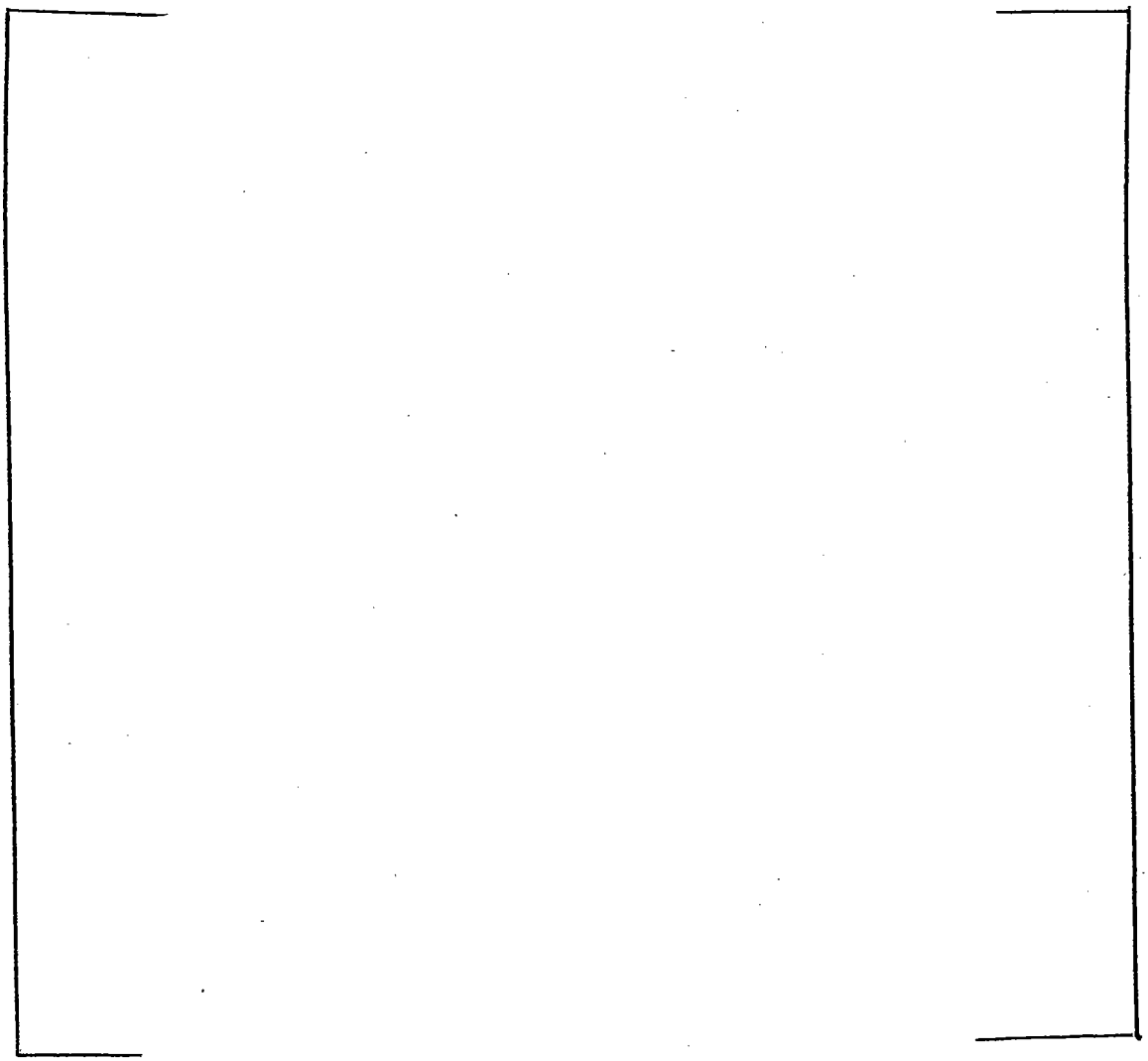
7.

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 RM
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]

NOV 0 6 2002
OGD / CDER

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information from

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

ANDA 75-139/S-005 [redacted] source Ibuprofen USP 200 mg White Film Coated Tablets
ANDA 75-010/S-004 [redacted] source 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 16, 2003

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

SUPPL AMENDEMENT
SCC-065-Am

Amendment to Supplement: Add Alternate Source [redacted] Ibuprofen
ANDA 75-139/S-005; Ibuprofen USP, 200 mg Tablets (RLD – Motrin)
ANDA 75-010/S-004; Ibuprofen USP, 200 mg Tablets (RLD – Advil)

Dear Dr. Patel:

This amendment is in response to the deficiency letter dated October 3, 2002 for a supplement, dated April 22, 2002, to add an alternate supplier, [redacted] for the drug substance Ibuprofen. LNK had submitted two separate supplements to qualify alternate suppliers [redacted] of the Active Pharmaceutical Ingredient (API) to both of our ANDAs for Over-the-Counter Ibuprofen. This amendment will respond to all the deficiencies for the Ibuprofen source from [redacted]. The deficiencies for the Ibuprofen source from [redacted] has already been responded to in the amendment dated November 6, 2002 and approved February 4, 2003.

Deficiencies

[redacted]

RECEIVED
MAY 20 2003
OGD / CDER
0001

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

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information from

5/16/2003 LNK LETTER

11. Please compare your

[redacted]

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.