CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74931

CORRESPONDENCE

Lodhiana

ANDA 74-931

JAN - 2 1997

Granutec Inc.
Attention: Thérèse Ast, Ph.D., Esq.
U.S. Agent for: Novopharm Limited
4409 Airport Drive N.W.
Wilson NC 27896

Dear Madam:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Ibuprofen Tablets USP, 200 mg.

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

2. The dissolution testing will need to be incorporated into your stability and quality control programs as specified in USP 23.

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

/S/

Rabindra Patnaik, Ph.D.
Acting Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

novopharm
Novopharm Limited
5691 Main Street, Stouffville, Ontario, Canada L4A 1H5
Telephone (905) 642-4550
Fax (905) 642-4591

Office of Generic Drugs
Center for Drug Evaluation and Research
Food & Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

MINOR AMENDMENT

NDA ORIG AMENDMENT

RE: **ANDA # 74-931**
IBUPROFEN TABLETS USP, 200 MG (ROUND AND CAPSULE-SHAPED)

We thank you for your letters which we received on January 20, 1997 from Dr. Rashmikant M. Patel, of the Division of Chemistry I, and Mr. Jerry Phillips, of the Division of Labeling and Program Support. These letters were in response to our July 31, 1996 Abbreviated New Drug Application for Ibuprofen Tablets USP, 200 mg.

For ease of review, Dr. Patel's and Mr. Phillip's comments have been restated in **bold** print, followed by our response.

Enclosed are one (1) archival, one (1) review and one (1) field copy of this Minor Amendment. We certify that the field copy is a true copy of the technical sections contained in the archival and review copies of this Amendment and that the field copy has been submitted to the Office of Generic Drugs.

Should you have any further comments or questions, please do not hesitate to contact Novopharm by telephone at 1-800-361-3313 or by fax at (905) 642-4590.

Yours sincerely,

Dietrich Bartel

JUN 27 1997

Dietrich Bartel, B.Sc.
Manager, Pre-Approval
U.S. Regulatory Affairs
NOVOPHARM LIMITED

(date)

cc: Dr. Thérèse M. Ast, Ph. D., Esq., U.S. Agent, Novopharm N.C. Inc.,
4700 Novopharm Blvd., Wilson, N.C. 27893

RECEIVED
JUN 30 1997
GENERIC DRUGS

Via Purolator (Waybill # 4001 321 0782)

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GENERIC DRUGS

Nadine 7-9-97

MEMBER CDMA

NOTED
1/24/97

novopharm
Novopharm Limited
5691 Main Street, Stouffville, Ontario, Canada L4A 1H5

Telephone (905) 642-4550
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NEW CORRESP
NC

January 21, 1997

Office of Generic Drugs, CDER
Food and Drug Administration
Document Control Room
Metro Park North II (MPN II)
7500 Standish Place
Room 150
Rockville, MD
U.S.A. 20855-2773

ACKNOWLEDGEMENT

SUBJECT: **ANDA 74-931**
Ibuprofen Tablets USP, 200 mg

We thank you for your facsimile amendment which we received on January 20, 1997 from Rashmikant M. Patel, Ph.D. of the Division of Chemistry I and Jerry Phillips of the Division of Labeling and Program Support. We are presently addressing the comments listed and our responses will be forwarded promptly.

Should you have any further comments or questions, please do not hesitate to contact us directly at 1-800-361-3313 or our U.S. Agent, Dr. Thérèse Ast at 1-919-234-2231.

Yours sincerely,

Dietrich Bartel

Dietrich Bartel
Manager, Pre-Approval
U.S. Regulatory Affairs

cc: Dr. Thérèse Ast (Novopharm NC Inc, 4700 Novopharm Blvd., Wilson, NC 27893)

Via Purolator (Waybill # 4001 321 0758)

MEMBER

novopharm
Novopharm Limited
5691 Main Street, Stouffville, Ontario, Canada L4A 1H5
Telephone (905) 642-4550
Fax (905) 642-4591

9/4/96

RECEIVED
AUG 1 1996
GENERIC DRUGS

ANDA

Office of Generic Drugs
Center for Drug Evaluation and Research
Food & Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: **Abbreviated New Drug Application**
IBUPROFEN TABLETS USP, 200 MG
(ROUND AND CAPSULE-SHAPED)

We are pleased at this time to submit an original Abbreviated New Drug Application for our product - Ibuprofen Tablets USP, 200 mg (round and capsule-shaped).

The purpose of this application is to gain FDA approval to market Ibuprofen Tablets USP, 200 mg (round and capsule-shaped) in the U.S.A. The drug product described above is the same as NUPRIN®, 200 mg manufactured by Bristol-Myers Squibb Co. We have submitted comparative information to indicate that our product is the same as the reference listed drug product. This information is presented in tabular form, comparing active ingredient, conditions of use, route of administration, dosage form, strength, bioequivalence, and labeling for the products as supplied by Novopharm Limited and by Bristol-Myers Squibb Co.

We have enclosed one (1) archival, one (1) review, and one (1) field copy of the application in accordance with 21 CFR § 314.55. As required, three (3) additional separately bound copies of the analytical methods and descriptive information needed to perform the tests on the samples (both the bulk active ingredient and finished dosage form) are included as one of the volumes of the archival copy of this ANDA. The number of volumes in the archival, review, and field copies of the ANDA are as follows:

Blue Archival Copy	- 11 volumes
Orange Review Copy	- 9 volumes
Red Review Copy	- 3 volumes
Burgundy Field Copy	- 3 volumes

We certify that the Field Copy is a true copy of the technical section contained in the archival and review copies of this application.

Cont'd .../2

MEMBER CDMA

In addition, for the Bioequivalence Section, we have enclosed the computer diskettes with the analytical data and bioavailability parameters in the format prescribed by the FDA. The diskettes for the fasting and fed bioavailability studies are located at the front of Section VI of the Orange Review Copy of this application. Hard copies of the diskette data are also included at the front of Section VI.

We trust the information submitted is sufficient for this Abbreviated New Drug Application to be evaluated. If there are any questions with respect to this application, you may direct written and telephoned communications to Dr. Thérèse Ast at (919) 291-9100 or you may contact Novopharm directly at 1-800-361-3313.

A letter of authorization, allowing Dr. Ast to act as our U.S. agent, is included in Section XXI. 2. b of this application.

Yours sincerely,

Dietrich Bartel

JUL 3 1 1996

(date)

Dietrich Bartel, B.Sc.
Manager, Pre-Approval
U.S. Regulatory Affairs
NOVOPHARM LIMITED

cc: Dr. Thérèse M. Ast, Ph. D., Esq.
U.S. Agent
Granutec Inc.
4409 Airport Drive N.W.
Wilson, N.C. 27896

Via PUROLATOR COURIER (Waybill # 401 064 6844)