CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76-200

CORRESPONDENCE

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

July 2, 2001

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

ORIGINAL ANDA SUBMISSION

RE: ANDA FOR ACETAMINOPHEN EXTENDED RELEASE (ER) TABLETS 650 mg

Dear Director, Office of Generic Drugs:

CorePharma LLC (CorePharma) submits today an original abbreviated new drug application ("ANDA") seeking approval to market a Acetaminophen Extended Release (ER) Tablets 650 mg which is bioequivalent to the listed drug, Tylenol® Arthritis Pain Caplets, manufactured by McNeil pursuant to NDA # 19-872.

This ANDA consist the following volumes:

Archival Copy	Blue Folders	5 volumes
Review Copy	Red Folders	2 volumes
Bioequivalence Copy	Orange Folder	3 volumes (Attached Data Diskettes)

For more detailed information on the organization of this ANDA, please refer to the ANDA, "Executive Summary - Organization of the ANDA attached." Since, Acetaminophen Extended Release Tablets 650 mg are non-compendial, enclosed two additional copies of Method Validation Reports (Sections 14.0 and 15.0). CorePharma commits to resolve any issues identified in the methods validation process after approval.

This also certifies that, concurrently with the filing of this ANDA, a true copy of the technical sections of the ANDA (including a copy of the 356h form and a certification that the contents are a true copy of those filed with the Office of Generic Drugs) was sent to our local New Jersey district office. The "field copy" was contained in a burgundy folder.

Paragraph IV Certification

With respect to U.S. Patent Numbers 4,820,522; 4,968,509 and 5,004,613 CorePharma LLC certifies that in its opinion and to the best of its knowledge, the patents will not be infringed by the manufacture, use, sale, or offer to sell of Acetaminophen Extended Release Tablets, for which this abbreviated new drug application is submitted.

(over)

Please direct any written communication regarding this ANDA to me at the above address. If you need to call or fax me, my telephone number is (732) 868 1090 and (732) 868 1091 (fax).

Thank you for your prompt handling of this submission.

Sincerely,

G. Mukteeshwar

Mukteeshwar Gande, M.S., R.Ph.
Vice President

APPEARS THIS WAY
ON ORIGINAL

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

July 2, 2001

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

Additional Correspondence

RE: Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200

NEW CORRESP

Dear Director, Office of Generic Drugs:

As per telephone request from Ms. Saundra Middleton this afternoon, CorePharma LLC (CorePharma) herewith enclosed a "Statement Concerning Notice to Patent Owner and NDA Holders" for Acetaminophen ER Tablets 650 mg, ANDA # 76-200.

Please direct any written communication regarding this ANDA to me at the above address. If you need to call or fax me, my telephone number is (732) 868 1090 and (732) 868 1091 (fax).

Thank you for your prompt handling of this submission.

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

CENTER FOR DRUG EVALUATION AND RESEARCH
JUL 31 2001
OGD

COREPHARMA LLC
215 Wood Avenue, Middlesex, NJ 08846
Phone: (732) 868 1090, Fax: (732) 868 1091

FAX TRANSMISSION

NEW CORRESP
NC

To:	Ms. Saundra Middleton, FDA	Fax:	(301) 594-1174
From:	Mr. Mukti Gande	Date:	7/30/01
Re:	Acetaminophen ER Tablets 650 mg, ANDA # 76-200	Pages:	2 Including Cover Page
CC:	N/A		

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Dear Ms. Saundra Middleton:

Subject: Additional correspondence to Acetaminophen ER Tablets 650 mg
ANDA # 76-200

As per your telephone request this afternoon, please find enclosed "Statement Concerning Notice to Patent Owner and NDA Holders" for Acetaminophen ER Tablets 650 mg, ANDA # 76-200.

If you have any other questions please do not hesitate to call me at (732) 868 1090.

Thank you very much for prompt handling this ANDA.

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

ANDA 76-200

AUG - 1 2001

CorePharma LLC
Attention: Mukteeshwar Gande
215 Wood Avenue
Middlesex, NJ 08846

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to the telephone conversation dated July 30, 2001 and your correspondence dated July 30, 2001.

NAME OF DRUG: Acetaminophen Extended-release Tablets, 650 mg

DATE OF APPLICATION: July 2, 2001

DATE (RECEIVED) ACCEPTABLE FOR FILING: July 5, 2001

You have filed a Paragraph IV patent certification, in accordance with 21 CFR 314.94(a)(12)(i)(A)(4) and Section 505(j)(2)(A)(vii)(IV) of the Act. Please be aware that you need to comply with the notice requirements, as outlined below. In order to facilitate review of this application, we suggest that you follow the outlined procedures below:

CONTENTS OF THE NOTICE

You must cite section 505(j)(2)(B)(ii) of the Act in the notice and should include, but not be limited to, the information as described in 21 CFR 314.95(c).

SENDING THE NOTICE

In accordance with 21 CFR 314.95(a):

- Send notice by U.S. registered or certified mail with return receipt requested to each of the following:

  1) Each owner of the patent or the representative designated by the owner to receive the notice;

2) The holder of the approved application under section 505(b) of the Act for the listed drug claimed by the patent and for which the applicant is seeking approval.

3) An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

DOCUMENTATION OF NOTIFICATION/RECEIPT OF NOTICE

You must submit an amendment to this application with the following:

- In accordance with 21 CFR 314.95(b), provide a statement certifying that the notice has been provided to each person identified under 314.95(a) and that notice met the content requirements under 314.95(c).

- In accordance with 21 CFR 314.95(e), provide documentation of receipt of notice by providing a copy of the return receipt or a letter acknowledging receipt by each person provided the notice.

- A designation on the exterior of the envelope and above the body of the cover letter should clearly state "PATENT AMENDMENT". This amendment should be submitted to your application as soon as documentation of receipt by the patent owner and patent holder is received.

DOCUMENTATION OF LITIGATION/SETTLEMENT OUTCOME

You are requested to submit an amendment to this application that is plainly marked on the cover sheet "PATENT AMENDMENT" with the following:

- If litigation occurs within the 45-day period as provided for in section 505(j)(4)(B)(iii) of the Act, we ask that you provide a copy of the pertinent notification.

- Although 21 CFR 314.95(f) states that the FDA will presume the notice to be complete and sufficient, we ask that if you are not sued within the 45-day period, that you provide a letter immediately after the 45 day period elapses, stating that no legal action was taken by each person provided notice.

You must submit a copy of a court order or judgement or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information. We ask that this information be submitted promptly to the application.

If you have further questions you may contact Gregg Davis, Chief, Regulatory Support Branch, at (301) 827-5862.

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Jeen Min
Project Manager
(301) 827-5848

Sincerely yours,

Gregory S. Davis for

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 76-200
cc: DUP/Jacket
Division File
Field Copy
HFD-610/R.West
HFD-610/P.Rickman
HFD-92
HFD-615/M.Bennett
HFD-600/
Endorsement:
HFD-615/GDavis, Chief, RSB GDavis 31-JUL-2001 date
HFD-615/SMiddleton, CSO S. Middleton date 7/30/01
Word File V:\FIRMSAM\COREPHARM\LTRS&REV\76200.ACK
F/T EEH 07/30/01
ANDA Acknowledgment Letter!

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

August 20, 2001

ORIG AMENDMENT

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

FAX
AMENDMENT
BIOEQUIVALENCE

Re: Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200

Dear Director:

This is in response to the Facsimile Deficiency received on August 7, 2001 for the Acetaminophen Extended Release (ER) Tablets 650 mg, ANDA # 76-200. We performed the in vitro dissolution profile as per OGD - Bioequivalence division recommendations and amended our application. As per the requirement, we faxed the Fax Amendment - Bioequivalence to Mr. Steven Mazzella, Project Manager at (301) 594 0181 and two copies have been mailed as Archival and Review copies.

Please direct any written communication regarding this submission to me at the above address. If you need to call or fax me, my telephone number is (732) 868 1090 and (732) 868 1091 (fax).

Please review the amendment and approve the application as soon as possible.

Thank you for your prompt handling of this submission.

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

CENTER FOR DRUG
AUG 2 1 2001
OGD

COREPHARMA LLC

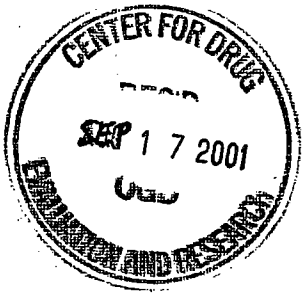
215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

September 12, 2001

NEW CORRESP

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

AMENDMENT TO A PENDING APPLICATION



Re: Acetaminophen Extended Release Tablets 650 mg
ANDA # 76-200
Amendment - Notice to Patent Holders

Dear Director:

Reference is made to the pending ANDA for Acetaminophen Extended Release Tablets 650 mg.

Corepharma LLC has completed with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner of said patents or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95 (c) with respect to the content of the notice.

We are amending the application to certify that we have notified the appropriate holder. The letters sent to William McComb, President, McNeil Consumer Healthcare and Philip S. Johnson, Esq., Chief Patent Counsel, Johnson & Johnson and sent on September 7th and 6th, 2001 respectively. Attached are copies of the certified receipts of the notices from the listed drug holder.

If you have any questions regarding this submission please contact me at (732) 868 1090.

Thank you for your prompt handling of this submission.

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

October 18, 2001

ORIG AMENDMENT
N 76
BIOAVAILABILITY
BIOEQUIVALENCY AMENDMENT

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

Re: Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200

Dear Director:

This is in response to the deficiency received on October 10, 2001 for the Acetaminophen Extended Release (ER) Tablets 650 mg, ANDA # 76-200. We performed the *in vivo* bioequivalence studies in Fasting and Fed conditions. The details of the response are enclosed in enclosed documents. As per the requirement, we faxed the Bioequivalency Amendment to Mr. Steven Mazzella, Project Manager at (301) 594 0181 and two copies have been mailed as Archival and Review copies.

Please direct any written communication regarding this submission to me at the above address. If you need to call or fax me, my telephone number is (732) 868 1090 and (732) 868 1091 (fax).

Please review the amendment and approve the application as soon as possible.

Thank you for your prompt handling of this submission.

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

CENTER FOR DRUG EVALUATION AND RESEARCH
OCT 19 2001
OGD

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

November 5, 2001

NAF mtk 11/8/01

NEW CORRESP
NC

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

AMENDMENT TO A PENDING APPLICATION

Re: Acetaminophen Extended Release Tablets 650 mg
ANDA # 76-200
Amendment – No Response from Patent Holder to Notification of filing ANDA 76-200

Dear Director:

We are submitting an amendment to Corepharma, LLC's pending ANDA 76-200 for Acetaminophen Extended Release Tablets 650 mg in accordance with 21 CFR 314.95.

Corepharma LLC has complied with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner of said patents or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95 (c) with respect to the content of the notice. We notified the appropriate holders on September 7th, 2001 and received the certified receipt of the notice from the listed drug holder, McNeil Consumer Healthcare.

As of today, (more than 45 days), McNeil has not filed suit against Corepharma LLC, regarding the submission of ANDA 76-200.

Thank you very much for prompt handling of this submission.

If there are any questions regarding this submission please contact me at (732) 868 1090.

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

CENTER FOR DRUG EVALUATION
NOV 06 2001

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

December 7, 2001

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

MINOR AMENDMENT

ORIG AMENDMENT
N/A M

Re: Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200

Dear Director:

This is in response to the Minor Amendment Letter Dated: November 29, 2001. We have included FDA's recommendations for chemistry, labeling and bioequivalence sections of the application.

Please find enclosed final printed container labels (12 labels each for 24s, 100s, 150s and 500s bottles) and carton labels (12 labels each for 24s, 100s and 150s) for your review.

Please direct any written communication regarding this submission to me at the above address. If you need to call or fax me, my telephone number is (732) 868 1090 and (732) 868 1091 (fax).

Sincerely,

Mukteeshwar Gande, M.S., R.Ph.
Vice President

CENTER FOR DRUG EVALUATION AND RESEARCH
DEC 10 2001
OGD

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

February 5, 2002

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

TELEPHONE AMENDMENT

ORIG AMENDMENT

Re: Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200

Dear Director:

This is in response to the Telephone Amendment conveyed to us on February 5, 2002. We included OGD's recommendations for the chemistry section of the application.

This also certifies that a True Copy of this submission (including a copy of the 356h form) was sent to our local New Jersey district office.

Please direct any written communication regarding this submission to me at the above address. If you need to call or fax me, my telephone number is (732) 868 1090 and (732) 868 1091 (fax).

Sincerely,

G. Mukteeshwar

Mukteeshwar Gande, M.S., R.Ph.
Vice President

CENTER FOR DRUG EVALUATION AND RESEARCH
FEB 06 2002
OGD

COREPHARMA LLC

215 Wood Ave., Middlesex, NJ 08846
(732) 868-1090 Fax: (732) 868-1091
Web: http://www.corepharma.com

March 18, 2002

Noted, NAT
3/19/2002

Robert L. West, R.Ph., M.S.
Director, Division of Labeling and Program Support
Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

Re: Acetaminophen Extended Release Tablets 650 mg
ANDA # 76-200
Clarification of NDA Holder and Patent Holder

Dear Mr. West:

As per your request, we verified and confirmed that McNeil is the Patent holder as well as the NDA holder for Tylenol® Arthritis Tablets 650 mg. Please find enclosed copies of the first pages of all three listed patents (US Patents # 4,820,522; 4,968,509 and 5,004,613) and a copy of the "Orange Book" page for your verification.

If you have any questions regarding this submission please contact me at (732) 868 1090.

Thank you very much for your cooperation.

Sincerely,

G. Mukteeshwar

Mukteeshwar Gande, M.S., R.Ph.
Vice President