CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-268

Correspondence

Electronic Mail Message

Date: 6/25/01 1:32:10 PM
From: Athey, Judy (Judy.Athey@unimed.solvay.com)
To: 'birdsongs@cder.fda.gov' (birdsongs@A1)
Cc: Gallo, Frank (Frank.Gallo@solvay.com)
Cc: Outwater, Robert (Robert.Outwater@unimed.solvay.com)
Cc: Vlasak, Kelly (Kelly.Vlasak@unimed.solvay.com)
Cc: [( ]
Subject: NDA 21-268

Dear Ms. Birdsong:

As requested by telephone on 18 June 2001 and clarified on 25 June 2001, following is a statement regarding published literature in NDA 21-268.

Teveten® HCT (eprosartan/hydrochlorothiazide) NDA 21-268 was submitted 30 August 2000 and included eight adequate and well-controlled clinical studies.

The NDA also included published literature references related to the data discussed in the clinical section of the NDA. These published literature references alone are not sufficient to support approval of Teveten® HCT.

Judy Athey
Manager, Regulatory Affairs
June 2001

Judy Athey
Manager, Regulatory Affairs
Unimed Pharmaceuticals, Inc.
Four Parkway North, Suite 200
Deerfield, Illinois 60015-2544
847-282-5423 telephone 847-282-5740 fax
judy.athey@unimed.solvay.com
http://www.unimed.com

UNIMED
PHARMACEUTICALS, INC.
A Solvay Pharmaceuticals, Inc. Company

Unimed Pharmaceuticals, Inc.
Four Parkway North, Suite 200
Deerfield, IL 60015
847-282-5400
847-282-5740 FAX

FAX . . .

Date:	09 July 2001	**No. of Pages:**	1
To:	Sandy Birdsong, Project Manager	**From:**	Judy Athey
	Division of Cardio-Renal Drug Products, HFD-110		Manager, Regulatory Affairs
Phone:	301-594-5334	**Phone:**	847-282-5423
Fax:	301-594-5495	**Fax:**	847-282-5740

Dear Ms. Birdsong:

This communication is to provide the Division with a list of participants for a teleconference between Drs. Lipicky, Stockbridge and Unimed Pharmaceuticals, Inc. regarding the proposed labeling for NDA 21-268, Teveten® (esprosartan mesylate/hydrochlorothiazide).

The teleconference is scheduled for 3:30-5:00 p.m. (Eastern Standard Time). The dial in number for the teleconference is 800-621-1914; participant code is 143267.

Following are participants for Unimed:

Judy Athey, Unimed Pharmaceuticals, Inc.

[ ]

Henk Pluim, Ph.D., Solvay BV
Claus Steinborn, M.D., Solvay BV
Frans Coenen, Ph.D., Solvay BV

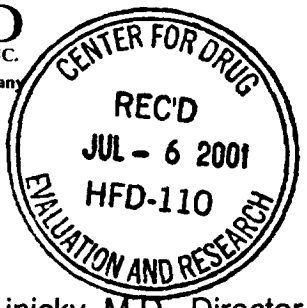
Please telephone me if you have questions.

Judy Athey
Signature

09 July 2001
Date

Four Parkway North
Deerfield, IL 60015-2544
847-282-5400
Fax 847-374-8480

UNIMED
PHARMACEUTICALS, INC.
A Solvay Pharmaceuticals, Inc. Company



05 July 2001

Raymond J. Lipicky, M.D., Director
Division of Cardio-Renal Drug Products, HFD-110
Food and Drug Administration
Woodmont Office Complex 2, Room 5039
1451 Rockville Pike
Rockville, MD 20852

RE: TEVETEN® HCT (eprosartan mesylate/hydrochlorothiazide) Tablets
NDA 21-268
General Correspondence: Notification of Intent to File Amendment

Dear Dr. Lipicky:

Reference is made to Unimed Pharmaceuticals, Inc., pending NDA 21-268 for TEVETEN® HCT (eprosartan mesylate/hydrochlorothiazide) 600/12.5 and 600/25 mg Tablets, submitted 30 August 2000 and to the Agency's approvable letter of 27 June 2001. Unimed intends to file an amendment to this application as soon as the information is available to address the Agency's comments.

Should you have any questions about the information contained in this submission, please contact me at 847-282-5423.

Sincerely,

Judy Athey
Manager, Regulatory Affairs

Enclosures

cc: Sandy Birdsong, Project Manager, FDA (cover letter only)

Four Parkway North
Deerfield, IL 60015-2544
847-282-5400
Fax 847-374-8480

UNIMED
PHARMACEUTICALS, INC.
A Solvay Pharmaceuticals, Inc. Company

May 24, 2001

Raymond J. Lipicky, M.D., Director
Division of Cardio-Renal Drug Products, HFD-110
Food and Drug Administration
Woodmont Office Complex 2, Room 5039
1451 Rockville Pike
Rockville, MD 20852

Re: Teveten®HCT
(eprosartan mesylate/hydrochlorothiazide) Tablets
IND[ ] Serial Number 435
General Correspondence: Final Study Report

Dear Dr. Lipicky:

Reference is made to Unimed Pharmaceuticals, Inc. New Drug Application 21-268 dated 30 August 2000 for Teveten® HCT (eprosartan mesylate/hydrochlorothiazide) Tablets and to the 25 April 2001 submission of a Final Bioavailability Study Report for Study CR 1711006.01: *A Randomized, Single-Dose, Two-Period, Cross-Over Study to Compare the Bioavailability of One Combination Tablet of Eprosartan 600 mg/Hydrochlorothiazide 25 mg Relative to the Coadministration of One 600 mg Eprosartan Tablet and One 25 mg Hydrochlorothiazide Tablet in Healthy Male and Female Volunteers.*

Draft summary reports were submitted to IND[ ]on 15 May 2001 in response to a telephone request on 07 May 2001 by Drs. Patrick Marroum and Angelica Dorantes, Biopharmaceutics Reviewers for NDA 21-268, Teveten® HCT.

The purpose of this submission is to provide a Final Study Report for *The Determination of Eprosartan in*[ ]which contains the method validation for the analysis of eprosartan; and *The Determination of Hydrochlorothiazide in*[ ]which contains the method validation for the analysis of hydrochlorothiazide.

Should you have any questions or need additional information, please contact me at (847) 282-5423.

Sincerely,

Judy Athey

Judy Athey
Manager, Regulatory Affairs

Attachment

cc: Sandy Birdsong, Project Manager, FDA (cover letter only)

423-989-8055DIVISION OF CARDIO-RENAL DRUG PRODUCTS
FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SE

US Mail address:
FDA/CDER/HFD-110
5600 Fishers Lane
Rockville, MD 20857

Woodmont II
1451 Rockville Pike
Rockville, MD 20852

Transmitted to FAX Number:	847-282-5740
Attention:	**Mr. Michael O'Beirne**
Company Name:	**Unimed Pharmaceuticals, Inc.**
Phone:	847-282-5449
Subject:	Trade Name Decision
Date:	January 26, 2001
Pages including this sheet:	1
From:	Sandy Birdsong
Phone:	301-594-5334
Fax:	301-594-5494

Dear Mr. O'Beirne:

As per your request, this is to confirm information given to you by telephone on January 12, 2001. The Office of Post-Marketing Drug Risk Assessment has completed their proprietary name review and does not recommend the use of the proposed proprietary name, Teveten, but has no objections to the use of the alternate name, Teveten HCT. Additionally, this is to inform you that your proposed proprietary name must be re-evaluated by OPDRA approximately 60 days (and not more than 90 days) prior to the approval of the application.

Sincerely,
Sandy Birdsong, Regulatory Health Project Manager