CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-315

CORRESPONDENCE

Beth Brannan, Director
Drug Regulatory Affairs

Geneva Pharmaceuticals, Inc.
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Geneva pharmaceuticals, inc.

ORIG AMENDMENT
N/ATM

FEDERAL EXPRESS

Douglas Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Metro Park North 2, Room 150
7500 Standish Place
Rockville, MD 20855

MINOR AMENDMENT

OCT 14 1998

RE: ANDA 74-315 Terazosin Hydrochloride Tablets1 mg, 2 mg, 5 mg and 10 mg Minor Amendment – Chemistry and Manufacturing Controls: Updates/Request for Full Approval at Expiration of 30-Month Waiting Period

Dear Director:

Geneva Pharmaceuticals Inc. ("Geneva") hereby submits this minor amendment to its tentatively approved Abbreviated New Drug Application for Terazosin Tablets 1 mg, 2 mg, 5 mg and 10 mg, ANDA 74-315, in order to request full approval in accordance with Section 505(j) of the Food, Drug and Cosmetic Act ("FDCA") and 21 CFR 314.

Reference is made to your communication dated June 17, 1997.

1. Per Section 505(j) (4)(B)(iii) of the FDCA and your communication dated June 17, 1997, Geneva requests full approval of ANDA 74-315 Terazosin Hydrochloride Tablets 1 mg, 2 mg, 5 mg and 10 mg upon the expiration of the 30-month waiting period which expires November 4, 1998.

Geneva's ANDA contains a Paragraph IV certification for U.S. Patent No. 5,504,207 certifying that Abbott Laboratories' U.S. Patent Number 5,504,207 which expires on April 29, 2013, is invalid or will not be infringed by the manufacture, use or sale of the Geneva Products, and the date the notice was received by Abbott as indicated by the return receipt (May 3, 1996), we calculate that the 30-month waiting period will expire November 4, 1998. Therefore, we request that full approval be granted at the expiration of the 30-month waiting period on November 4, 1998.

2. We would like to take this opportunity to report the following additional updates which have been made to Terazosin Hydrochloride Tablets 1 mg, 2 mg, 5 mg and 10 mg documents.

10/14/98

Inactive Raw Material Specifications and Methods

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed stamped envelope.

Sincerely,

GENEVA PHARMACEUTICALS, INC.

Beth Brannan

Beth Brannan, Director
Drug Regulatory Affairs

Enclosures
BB/ap

4.1

ANDA 74-315

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2555 W. Midway Blvd.
Broomfield CO 80038-0446

JUL 9 1996

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 Terazosin Hydrochloride Tablets 1 mg, 2 mg, 5 mg and 10 mg.

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

2. The following dissolution testing will need to be incorporated into your stability and quality control programs:

   The dissolution testing should be conducted in 900 mL of water at 37°C using USP 23 apparatus 2 (Paddle) at 50 rpm. The test should meet the following specifications:

   Not less than of the labeled amount of the drug in the tablet dissolved in 30 minutes.

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/

Keith K. Chan, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Geneva pharmaceuticals, inc.

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505(j)(2) Paper NDA 1/27/93

FEDERAL EXPRESS

January 12, 1993

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JAN 1 [illegible]

GENERIC DRUGS

Roger Williams, M.D., Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Metro Park North 2, Room 150
7500 Standish Place
Rockville, MD 20855

RE: Terazosin Hydrochloride Tablets, 1 mg, 2 mg, 5 mg and 10 mg

Dear Dr. Williams:

Geneva Pharmaceuticals, Inc. is hereby submitting an Abbreviated New Drug Application for Terazosin Hydrochloride Tablets, 1 mg, 2 mg, 5 mg and 10 mg as required by Section 505 of the Federal Food, Drug, and Cosmetic Act.

A comprehensive table of contents is provided which shows the volume and page number of our submission's contents, as required by the regulations part 314.94(a)(1).

The blue archival copy contains the complete application. Additionally, the blue archival copy contains a method validation package. Triplicate copies of raw material and finished product specifications have been placed in a plastic sleeve, located just inside the cover.

The red review copy contains labeling and the technical portion of our application. The orange review copy contains bioequivalence information. A bioequivalence study has been completed comparing Geneva's Terazosin Hydrochloride Tablets, 5 mg to Hytrin®, 5 mg. A full copy of the study and requests for waiver for the 1 mg, 2 mg and 10 mg strength products are provided.

This information is submitted for your review and approval.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and return it in the self-addressed stamped envelope.

Sincerely,

GENEVA PHARMACEUTICALS, INC.

Beth Brannan

Beth Brannan, Director
Drug Regulatory Affairs

Enclosures