

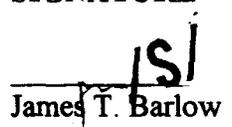
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74530

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

<p>I telephoned Zenith on Feb 1, 2000 to let them know that their labeling had to be changed(HOW SUPPLIED) section to be in accordance with their Controls for Finished Dosage. See the amendment sent on January 14, 2000 pertaining the dissolution test. I did not speak with anyone but was forwarded to Pat Jaworski's voice mail. I asked her to call me before any changes were made to avoid confusion</p>	DATE Feb 1, 2000
	APPLICATION NUMBERS 74-530
	IND NUMBER
	TELECON
	INITIATED BY __APPLICANT / SPONSOR
	<input checked="" type="checkbox"/> FDA
	PRODUCT NAME Terazosin HCL tablets
	FIRM NAME Zenith-Goldline Pharmaceuticals, Inc.
	NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Pat Jawarski
	TELEPHONE NUMBER 201-767-1700 ext. 331
SIGNATURE  James T. Barlow	

cc:

ANDA: 75-256/SL-001
DUP/DIVISION FILE

RECORD OF TELEPHONE CONVERSATION

<p>On January 24, 2000 I telephoned Zenith-Goldline's answering service for Jason Gross and I left a message about ANDA 74-580 for Terazosin HCL pertaining to the new embossing/debossing on their tablet and the different manufacture code they will utilize. In their January 14, 2000 amendment they indicate that they will be switching back to the original submission embossing/debossing code, however, the package insert has already been approved utilizing the updated product specifications. I left a message to call me as soon as possible.</p> <p align="center"><i>3-11-00 Pat J. Barlow</i></p>	DATE Jan 24, 2000
	APPLICATION NUMBERS 74-580 74-580
	IND NUMBER
	TELECON
	INITIATED BY __APPLICANT / SPONSOR
	<input checked="" type="checkbox"/> FDA
	PRODUCT NAME Terazosin HCL Tablets 1 mg, 2 mg, 5 mg and 10 mg.
	FIRM NAME Zenith-Goldline Pharmaceuticals, Inc.
	NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Answering service
	TELEPHONE NUMBER 201 767-1700/ext 331
SIGNATURE  James Barlow	

cc:

ANDA: 74-580
DUP/DIVISION FILE

PATENT CERTIFICATION

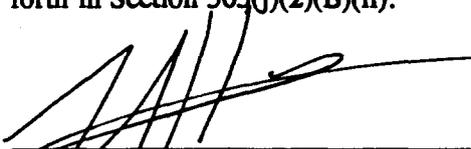
Based upon information published in the "Approved Drug Products with Therapeutic Equivalents Evaluations", 17th Edition, and the letter dated July 8, 1997 from Douglas L. Sporn, Director, Office of Generic Drugs, to Zenith Goldline Pharmaceuticals, Inc. ("Zenith"), pursuant to Section 505(j)(2)(A)(vii) of the Federal Food, Drug and Cosmetic Act ("the Act"), Zenith hereby submits the following certifications with respect to United States Patents Nos. 5,412,095 and 5,504,207, each expiring on April 29, 2013:

U.S. Patent No. 5,412,095 - Paragraph IV Certification

Zenith hereby certifies that, in its opinion and to the best of its knowledge, this patent is unenforceable against Zenith and will not be infringed by the manufacture, use or sale of the terazosin hydrochloride product for which Zenith's ANDA 74-530 is submitted, based upon a covenant not to use under such patent granted to Zenith by the patent owner, Abbott Laboratories. Zenith will comply with the notification requirements set forth in Section 505(j)(2)(B)(i) of the Act, and the content of such notice will conform to the requirements set forth in Section 505(j)(2)(B)(ii).

U.S. Patent No. 5,504,207 - Paragraph IV Certification

Zenith hereby certifies that, in its opinion and to the best of its knowledge, this patent is unenforceable against Zenith and will not be infringed by the manufacture, use or sale of the terazosin hydrochloride product for which Zenith's ANDA 74-530 is submitted, based upon a covenant not to use under such patent granted to Zenith by the patent owner, Abbott Laboratories. Zenith will comply with the notification requirements set forth in Section 505(j)(2)(B)(i) of the Act, and the content of such notice will conform to the requirements set forth in Section 505(j)(2)(B)(ii).



Jason A. Gross, Pharm.D.
Director, Regulatory Affairs
Zenith Goldline Pharmaceuticals, Inc.

4/9/98

Date

RECORD OF TELEPHONE CONVERSATION

<p>Reference is made to the minor amendment dated 12Feb97. The telecon was initiated by FDA to comment on the following product impurity specifications:</p> <p>INDIVIDUAL UNKNOWN OR ALL TOTAL UNKNOWNNS:</p> <p>A spec needs to be established for one or the other. The following limits may be acceptable depending upon the data: individual unknown impurities (e.g., 0.2%) or all total unknowns (e.g., 0.4%). FDA prefers limits for individual unknown.</p> <p>RELEASE AND STABILITY:</p> <p>The data do not support the proposed % limit for individual impurities. A smaller limit is recommended. A % limit may be acceptable depending upon the data.</p> <p>Dr. Warren will review the data and submit revised specifications (and rational) by fax for review prior to submitting a t-amendment.</p> <p>cc: NDA Division File T-con Binder</p>	<p>DATE</p> <p>3/4/97</p>
	<p>ANDA NUMBER</p> <p>74-530</p>
	<p>IND NUMBER</p>
	<p>TELECON</p>
	<p>INITIATED BY FDA Paul Schwartz Naiqi Ya Joseph Buccine</p>
	<p>PRODUCT NAME</p> <p>Terazosin HCl Tab</p>
	<p>FIRM NAME Zenith Goldline Pharmaceuticals, Inc.</p>
	<p>NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Vincent Warren Joan Janulis</p>
	<p>TELEPHONE NUMBER (201) 767-1700</p>
<p>SIGNATURE Joseph Buccine <i>JB 3/4/97</i></p>	

MINUTES OF PHONE CALL

DATE: April 18, 1997

SUBJECT: ANDA 74-530, Terazosin HCl Tablets

ORGANIZATION: Zenith Goldline

PARTICIPANTS: Allen Rudman
Karen Rocco

Karen was informed that there needs to be a routine in-process blend assay incorporated into the application due to the low dose of the drug product. The application currently called for blend assay only on the first three validation batches.

Karen agreed to this and said that she would send it in along with the patent information the Joe Buccine had requested sometime next week. I thanked her and said that next week would be fine.

**APPEARS THIS WAY
ON ORIGINAL**