

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74530

CHEMISTRY REVIEW(S)

Potency	Batch #	Yield Theoretical	Yield Actual
1 mg	ND-190		
2 mg	ND-192		
5 mg (Bio-batch)	ND-193		
10 mg	ND-194		

DMF Terazosin Hydrochloride remains adequate.

DMF was reviewed by this chemist. indicates that they will no longer manufacture Terazosin HCl but will continue to manufacture the intermediate,

PROPOSED PRODUCTION BATCH (MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?):

The proposed batch sizes are as follows:

1 mg tablets: units
 2 mg tablets: units
 5 mg tablets: units
 10 mg tablets: units

All batches are within a 10X increase and will be produced in the same manner as the bio-batch.

CHEMIST: David J. Cummings
 DATE: February 22, 2000

cc: ANDA 74-530
 ANDA DUP
 DIV FILE
 Field Copy

Endorsements:

HFD-623/DJCummings/
 HFD-623/AMueller, Ph.D

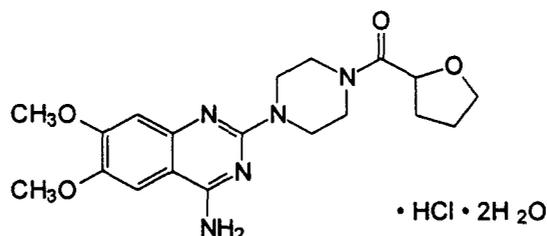
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 2/22/2000

OFFICE OF GENERIC DRUGS
ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMISTRY REVIEW NUMBER: 7
2. ANDA NUMBER: 74-530
3. NAME AND ADDRESS OF APPLICANT:
Zenith Goldline Pharmaceuticals, Inc.
Attention: Pat Jawarski
140 Legrand Avenue
Northvale, NJ 07647
4. LEGAL BASIS for ANDA SUBMISSION:
Patent Certification is provided in the original submission dated 8/1/94, on pages 007 through 014.
5. SUPPLEMENT(s): NA
6. PROPRIETARY OF DRUG: NA
7. NONPROPRIETARY NAME
Terazosin Hydrochloride Tablets
8. SUPPLEMENT(s) PROVIDE(s) FOR: NA
9. AMENDMENTS AND OTHER DATES:
08/1/1994 Date of Submission
09/12/1994 Amendment to ANDA
01/5/1995 Deficiency Letter (CMC)
07/18/1995 Major Amendment
08/7/1995 New Correspondence
03/20/1996 Deficiency Letter (CMC)
04/25/1996 Minor Amendment
08/29/1996 Minor Amendment
01/8/1997 Minor Amendment
02/12/1997 Minor Amendment (labeling)
03/4/1997 Telecon with the applicant
03/12/1997 Telephone Amendment
04/18/1997 Telecon with applicant (Rudman)
04/24/1997 Telephone Amendment (blend assay)
07/8/1997 Deficiency Letter (Patent Certification)
02/27/1998 New Correspondence
04/9/1998 Minor Amendment (Patent Certification/Covenant Not to Sue)
06/3/1998 Minor Amendment
06/15/1998 Telephone Correspondence
06/16/1998 Fax Correspondence (Request for Meeting)
06/24/1998 FDA Correspondence
06/26/1998 Deficiency Letter

6/29/1998 Minor Amendment
8/14/1998 Tentative Approval
11/9/1999 Minor Amendment
01/14/2000 Fax Amendment
01/25/2000 Telephone Correspondence (Labeling)
02/01/2000 Telephone Correspondence (Labeling)
02/09/2000 Telephone Amendment (Labeling)

10. PHARMACOLOGICAL CATEGORY:
Antihypertensive
11. OTC/R: Rx
12. RELATED IND/NDA/DMF(s): See previous reviews and DMF checklist.
13. DOSAGE FORM: Tablets
14. POTENCY: 1 mg, 2 mg, 5 mg, and 10 mg
15. CHEMICAL NAME AND STRUCTURE:
C₁₉H₂₅N₅O₄•HCl•2H₂O. 459.93. Piperazine, 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-[(tetrahydro-2-furanyl)carbonyl]-, monohydrochloride, dihydrate. 70024-40-7. USAN 1993, page 622. ●



16. RECORDS AND REPORTS: NA
17. COMMENTS:
Previously reviewed by N. Ya (CR #5) on April 25, 1997. The 180-day exclusivity ends on January 1, 2000. The firm has provided updated information relating to labeling and CMC for the ANDA. A copy of the Court Decision is provided under Exhibit 1 (Amendment dated November 9, 1999).
18. CONCLUSIONS AND RECOMMENDATIONS: **APPROVABLE**
19. REVIEWER/DATE COMPLETED: David J. Cummings 02/08/2000
Revised: 02/22/2000

Redacted 9

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commercial

information

Chem Review #7