

**CENTER FOR DRUG EVALUATION AND
RESEARCH
75-273**

APPLICATION NUMBER:

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 75-273
3. NAME AND ADDRESS OF APPLICANT

Teva Pharmaceuticals USA
1510 Delp Drive
Kulpsville, PA 19443

4. LEGAL BASIS FOR SUBMISSION

The firm certifies that to the best of their knowledge and in their opinion there is one patent claims the listed drug.

U.S. Patent # 4335125 which expires June 15, 1999

The applicant will not engage in the commercial manufacture, use, or sale of the drug product until the expiration of U.S. Patent #4335125.

The firm certifies that to the best of their knowledge and in their opinion, there exists no listed exclusivities for the referenced drug product.

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|-------------------------------|---|
| 5. <u>SUPPLEMENT(s)</u> | 6. <u>PROPRIETARY NAME</u> |
| N/A | N/A |
| 7. <u>NONPROPRIETARY NAME</u> | 8. <u>SUPPLEMENT(s) PROVIDE(s) FOR:</u> |
| Ketoconazole | N/A |

9. AMENDMENTS AND OTHER DATES:

Amendment 3/23/99 (tentative to final)

10. PHARMACOLOGICAL CATEGORY

Treatment of systemic fungal infections

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

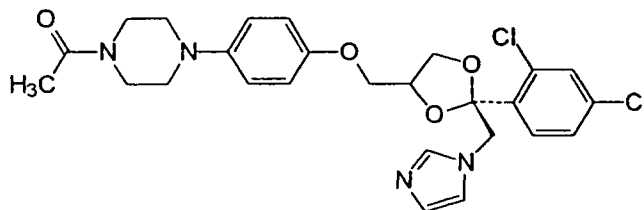
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| 13. <u>DOSAGE FORM</u> | 14. <u>POTENCY</u> |
|------------------------|--------------------|

Tablets

200 mg

15. CHEMICAL NAME AND STRUCTURE

Ketoconazole. Piperazine, 1-acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazole-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-, *cis*-. C₂₆H₂₈Cl₂N₄O₄. 531.44. 65277-42-1. Antifungal. USP 23, page 864.



17. COMMENTS

Previously (10/29/98) tentatively approved.

Minor modifications are acceptable.

DMF and EER are acceptable.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:

Nashed E. Nashed, Ph.D.

5/25/99

Supervisor: Paul Schwartz, Ph.D.

cc:

Endorsements:

HFD-627/NNashed/5/25/99

HFD-627/PSchwartz/5/28/99

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F/t by: gp/5/28/99

Handwritten signatures and dates:
Nashed 5/28/99
Schwartz 5/28/99

Page(s)

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Commercial/Confidential

Information and are not

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