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APPLICATION NUMBER:

75-429

CHEMISTRY REVIEW(S)

✓1. CHEMISTRY REVIEW NO. 6

2. ANDA # 75-429

3. NAME AND ADDRESS OF APPLICANT

TEVA Pharmaceuticals, USA
650 Cathill Road,
Sellersville, PA 18960

4. LEGAL BASIS FOR SUBMISSION

The listed drug is BETAPACE® Tablets, 80 mg, 120 mg, 160, mg and 240 mg of Berlex Laboratories. The applicant certified that in their opinion and to the best of their knowledge patent information has not been filed with the FDA.

The exclusivity for BETAPACE® Tablets expires October 30, 1999 and the applicant states that to the best of their knowledge no extension has been registered.

The applicant states that the drug product will not be made available for sale until the expiration of Orphan Drug Exclusivity on October 30, 1999.

See pp. 22 and 24 for patent and exclusivity statements.

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: N/A

7. NONPROPRIETARY NAME: Sotalol Tablets

8. SUPPLEMENT(s) PROVIDE FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Firm:

Submitted: July 31, 1998
Facsimile amendment: April 22, 1999
Telephone amendment: May 28, 1999
Telephone amendment: July 6, 1999
90 day amendment for final approval: Minor August 2, 1999
Facsimile amendment: October 20, 1999
Minor Amendment: January 31, 2000

FDA:

Acknowledgement: August 31, 1998
Facsimile deficiency letter: March 22, 1999
Telephone Conversation: May 14, 1999

17. COMMENTS

This application was tentatively approved in November 16, 1999. The firm submitted herewith a 90 day amendment for the final approval of this application. The approval letter will be issued.

18. CONCLUSIONS AND RECOMMENDATIONS

This application is considered as approvable. The approval letter will be issued.

19. REVIEWER:

Sema Basaran , Ph.D.

DATE COMPLETED:

March 17, 2000