

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40-275

CHEMISTRY REVIEW(S)

Office of Generic Drugs
Chemistry, Manufacturing and Controls Review

1. CHEMIST'S REVIEW NO.: No. 4

2. ANDA #: 40275

3. NAME AND ADDRESS OF APPLICANT:

ESI Lederle Inc.
P.O. Box 51502
Philadelphia, PA 19101

NAME OF RESPONSIBLE OFFICIAL OR AGENT:

Nicholas C. Tantillo
410 N. Middletown Road
Pearl River, NY 10965-1299

4. LEGAL BASIS FOR ANDA SUBMISSION:

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6. PROPRIETARY NAME:

None

7. NONPROPRIETARY NAME: Estradiol Tablets USP

8. SUPPLEMENT(S) PROVIDE(S) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

ESI Lederle:

08/29/97	Submission of ANDA (received on 09/02/97)
09/19/97	EVA Submission for Bioequivalence Data.
10/31/97	Sample Submission for Methods Verification
03/31/98	Major Amendment (Re: 02/23/98 CMC def. lett)
05/01/98	Bioequivalency Amendment (Re: 02/26/98 lett)
10/09/98	Facsimile Amendment
*12/07/98	Minor Amendment

FDA:

10/15/97	Acknowledgment letter
11/04/97	Labeling review completed.
12/3/97	Report for Methods Verification.
02/20/98	Chemistry-major deficiencies letter
02/26/98	Bioequivalency deficiencies
04/16/98	Labeling review completed-Acceptable
09/10/98	CMC review/Fax Amendment

09/19/98 Bio review completed-Acceptable
10/23/98 CMC review/Minor Amendment

10. PHARMACOLOGICAL CATEGORY:
Estrogen Replacement
11. Rx or OTC: Rx
12. RELATED IND/NDA/DMF(s):
Innovator: Bristol Myers Squibb
13. DOSAGE FORM: Tablets
14. POTENCY: 0.5 mg, 1.0 mg and 2.0 mg
15. CHEMICAL NAME AND STRUCTURE:
Estra-1,3,5(10)-trien-3,17 β -diol.
16. RECORDS AND REPORTS: N/A
17. COMMENTS:
- EER is still PENDING for overall recommendation.
 - The DMF is found to be ADEQUATE On 12/15/98.
 - Labeling review is completed, and it is ACCEPTABLE.
 - Bio review is completed, and it is ACCEPTABLE.
 - Review of this minor CMC amendment is completed. CMC closed and recommended to approval, pending for EER.
18. CONCLUSIONS AND RECOMMENDATIONS:
CMC closed and recommended to approval, pending for EER.
19. REVIEWER: Bing Cai, Ph.D. DATE COMPLETED: 12/15/98 DATE REVISED:

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev. 4

12/15/98