

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number NDA 21-310

CHEMISTRY REVIEW(S)

continues manner, over a period of 3-4 days. Three strengths of Alora® drug product have been approved since 1996 by the division of Reproductive and Urologic Drug Products (DRUDP), HFD-580, for the indication of hormone replacement therapy in post menopausal women. Per FDA request, a new NDA (21-310) is filed to this Division (HFD-510) in stead of a supplement to the already approved NDA (20-655), for the approval of all approved strengths and a new strength _____ mg) indicated for the prevention _____ of postmenopausal osteoporosis. _____ is manufactured by _____

Detailed information regarding the _____ has been submitted as Type II DMFs by _____

The drug substance for the new strength drug product is identical to the currently approved product (3 strengths of Alora® Transdermal System, NDA 20-655). The referenced DMFs have been previously reviewed and found adequate to support NDA 20-655, thus the CMC information is also adequate to support this NDA. The new _____ mg) strength is a 9 cm² patch containing the exact identical formulation and transdermal delivery system, with a proportionally reduced patch size, as the three strengths approved by DRUDP. Amendment dated 10/19/01 provided for EIC (Expected Introduction Concentration) and for clarification on the use of _____ in the drug product formulation. EERS were filed with the office of compliance for both the manufacturers of _____

_____ and the manufacturer of the drug product (Watson Laboratories, Inc.) and the facilities were found acceptable on 3-16-01, 3-8-01, and 3-20-01 respectively (see attached EES printout). An OPDRA consult for the trade name was not required since the product is already on the market with the trade name Alora.

CONCLUSIONS & RECOMMENDATIONS:

From chemistry standpoint, the NDA can be approved. The applicant should be reminded that only the drug products (4 strenths) containing _____ are approved for marketing, as indicated in the firms amendment dated 10/19/2001. In the package insert, the MW should be changed to 272.39 instead of _____

CC:
Org. NDA 21-310
HFD-510
HFD-510/EGChikhale
HFD-510/SW
HFD-510/DGWu/

R/D Init by: _____

Filename: 21310

Elsbeth G. Chikhale, Ph.D.
Review Chemist

**APPEARS THIS WAY
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/s/

Duu-gong Wu
10/25/01 07:55:57 PM
CHEMIST
Check-in for E. Chikhale

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