

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

20-655/S-008

**ADMINISTRATIVE DOCUMENTS**

**REQUEST FOR CONSULTATION**

TO: **Division of Drug Marketing, Advertising, and Communications (HFD 42)**  
**Attention: Lisa Stockbridge**  
Room # 17B23

FROM: HFD-580 (Division of Reproductive and Urologic Drug Products)  
Dornette Spell-LeSane, Regulatory Project Manager

DATE: <b>April 1, 2002</b>	IND NO.:	NDA NO.: <b>20-655</b>	TYPE OF DOCUMENT : <b>request for label review for supplemental NDA</b>	DATE OF DOCUMENT: <b>February 6, 2002</b>
NAME OF DRUG: <b>ALORA (Estradiol transdermal system)</b>	PRIORITY CONSIDERATION: <b>standard</b>	CLASSIFICATION OF DRUG: <b>HRT</b>	DESIRED COMPLETION DATE: <b>April 5, 2002</b>	

NAME OF FIRM: \_\_\_\_\_

**REASON FOR REQUEST**

**I. GENERAL**

- |                                                        |                                                  |                                                            |
|--------------------------------------------------------|--------------------------------------------------|------------------------------------------------------------|
| <input type="checkbox"/> NEW PROTOCOL                  | <input type="checkbox"/> PRE-NDA MEETING         | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER     |
| <input type="checkbox"/> PROGRESS REPORT               | <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> FINAL PRINTED LABELING            |
| <input type="checkbox"/> NEW CORRESPONDENCE            | <input type="checkbox"/> RESUBMISSION            | <input type="checkbox"/> LABELING REVISION                 |
| <input type="checkbox"/> DRUG ADVERTISING              | <input type="checkbox"/> SAFETY/EFFICACY         | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE       |
| <input type="checkbox"/> ADVERSE REACTION REPORT       | <input type="checkbox"/> PAPER NDA               | <input type="checkbox"/> FORMULATIVE REVIEW                |
| <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION | <input type="checkbox"/> CONTROL SUPPLEMENT      | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> MEETING PLANNED BY            |                                                  | <b>label Review</b>                                        |

**II. BIOMETRICS**

STATISTICAL EVALUATION BRANCH

- TYPE A OR B NDA REVIEW  
 END OF PHASE II MEETING  
 CONTROLLED STUDIES  
 PROTOCOL REVIEW  
 OTHER:

STATISTICAL APPLICATION BRANCH

- CHEMISTRY REVIEW  
 PHARMACOLOGY  
 BIOPHARMACEUTICS  
 OTHER:

**III. BIOPHARMACEUTICS**

- |                                                  |                                                     |
|--------------------------------------------------|-----------------------------------------------------|
| <input type="checkbox"/> DISSOLUTION             | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS  |
| <input type="checkbox"/> PHASE IV STUDIES        | <input type="checkbox"/> IN-VIVO WAIVER REQUEST     |

**IV. DRUG EXPERIENCE**

- |                                                                                  |                                                                              |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL             | <input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY |
| <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES | <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE                       |
| <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below)         | <input type="checkbox"/> POISON RISK ANALYSIS                                |
| <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP       |                                                                              |

**V. SCIENTIFIC INVESTIGATIONS**

CLINICAL

PRECLINICAL

**COMMENTS/SPECIAL INSTRUCTIONS:** Request for Label review. This label was reviewed and approved by DDMAC on November 8, 2001. The sponsor was asked to make additional revisions to the label to comply with today's class labeling. Please review and comment. Label attached  
cc: Original NDA 20-655

HFD-580/Div. Files  
HFD-580/Spell-LeSane/ Olmstead/Kober/Price/Chong/ Slaughter  
HFD-42/Stockbridge