

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER  
21-344**

**Chemistry Review(s)**

**NDA 21-344  
REVIEW # 1**

**FASLODEX (fulvestrant)  
INJECTION  
JOSEPHINE M. JEE  
REVIEW CHEMIST  
DIVISION OF ONCOLOGY  
DRUG PRODUCTS  
HFD-150/810  
CHEMISTRY,  
MANUFACTURING AND  
CONTROLS REVIEW**



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Chemistry Assessment Section

NDA 21-344 Review #1 FASLODEX (fulvestrant) Injection

# Chemistry NDA Review Data Sheet

1. NDA 21-344
2. REVIEW #: 1
3. REVIEW DATE: 16-JAN-2002
4. REVIEWER: JOSEPHINE M. JEE
5. PREVIOUS DOCUMENTS:

Previous DocumentsOriginal IND. Document Date

06-DEC-1996

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Original (Vol. 1.1 – 1.10)

Amendment [BC]

Amendment] [SU]

Amendment [BM]

Amendment [BM]

Amendment] [BS]

Amendment [C]

Amendment [BP]

Amendment [BC]

Amendment [BL]

Amendment [BP]

Amendment ]BP]

Lab. Insert Rev.

Document Date

28-MAR-2001

19-JUL-2001

20-JUL-2001

09-AUG-2001

28-AUG-2001

13-SEP-2001

18-OCT-2001

29-OCT-2001

09-NOV-2001

06-DEC-2001

11-DEC-2001

14-DEC-2001

06-MAR-2002

7. NAME & ADDRESS OF APPLICANT:

Name: 1800 Concord Pike  
IPR Pharmaceuticals, Inc. P.O. Box 8355  
Wilmington, DE 19803-8355



## CHEMISTRY REVIEW TEMPLATE



### Chemistry Assessment Section

NDA 21-344 Review #1 FASLODEX (fulvestrant) Injection

#### 8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: FASLODEX™
- b) Non-Proprietary Name (USAN): 7 $\alpha$ -[9-[(4,4,5,5,5-Pentafluoropentyl)sulfinyl]nonyl]estra-1,3,5(10)-triene-3,17 $\beta$ -diol
- c) Code Name/# (ONDC only): (ICI 182,780, ZD9238, fulvestrant)
- d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 1
  - Submission Priority: S

#### 9. LEGAL BASIS FOR SUBMISSION:

FASLODEX (IM) Injection, 250 mg/5 mL, IPR Pharmaceuticals, Inc.

#### 10. PHARMACOL. CATEGORY:

Antiestrogen (Treatment of Breast Cancer)

#### 11. DOSAGE FORM:

Intramuscular Injection

#### 12. STRENGTH/POTENCY:

250 mg/mL

#### 13. ROUTE OF ADMINISTRATION:

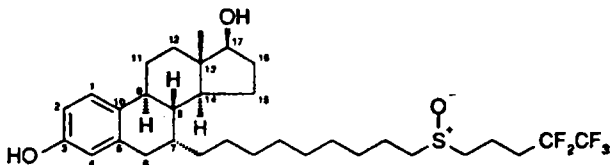
Intramuscular

#### 14. Rx/OTC DISPENSED: Rx OTC

#### 15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note21]:

N/A

#### 16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:



$C_{32}H_{47}F_5O_3S$

MW: 606.77

7 $\alpha$ -[9-[(4,4,5,5,5-Pentafluoropentyl)sulfinyl]nonyl]estra-1,3,5(10)-triene-3,17 $\beta$ -diol

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