

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-663

Microbiology Review(s)

Product Quality Microbiology Review

Review for HFD-580

5 October, 2004

NDA: 21-663

Drug Product Name

Proprietary: Menopur

Non-proprietary: Menotropins For Injection, USP

Drug Product Classification: 3S

Review Number: 21-663

Subject of this Review

	Original	Amendment	Amendment
Submission Date	Dec. 29, 2003	Sep. 17, 2004	Sep. 30, 2004
Receipt Date	Dec. 31, 2003	Sep. 20, 2004 FAX	Oct. 1, 2004 FAX
Consult Date	Jan. 2, 2004	Sep. 20, 2004	Oct. 1, 2004
Date Assigned for Review	Jan. 20, 2004	Sep. 20, 2004	Oct. 1, 2004

Submission History (for amendments in response to letters only)

Date(s) of Previous Submission(s):

Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: Ferring Pharmaceuticals, Inc.

Address: 400 Rella Boulevard, Suite 300
Suffern, NY 10901

Representative: James H. Conover, Ph.D.

Telephone: (845) 770-2668

Name of Reviewer: James L. McVey

Conclusion: The information provided is adequate to support approval from a product quality microbiology perspective.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** Not Applicable
 2. **SUPPLEMENT PROVIDES FOR:** Not Applicable
 3. **MANUFACTURING SITE:**
Cardinal Health (formerly SP Pharmaceuticals)
4272 Balloon Park Road, N.E.
Albuquerque, NM 87019
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** The single dose vial contains 75 IU each of FSH and LH in a lyophilized form. For administration dissolve 1 to 6 vials of Menopur in 1 to 2 mL of 0.9% Sodium Chloride Injection USP, and inject subcutaneously ζ immediately. One vial containing 2 mL of 0.9% Saline for Injection USP is supplied with each vial of Menopur.
 5. **METHOD(S) OF STERILIZATION:** ζ J
 6. **PHARMACOLOGICAL CATEGORY:** Hormones
- B. **SUPPORTING/RELATED DOCUMENTS:**
IND 53,954. A more purified form of Repronex (menotropins for injection). The drug product that is the subject of this review.
NDA 21-047. Repronex (menotropins for Injection) is the less purified form manufactured by this company at the same facilities.
NDA 21-289. Bravelle (urofollitropins for injection). The applicant stated that he manufacture of this drug product will be similar to Bravelle (approved May 6, 2002).
A Letter of Reference dated July 16, 2004 is provided on page 65 of Volume 9 for Cardinal Health Type V DMF Not Reviewed.
- C. **REMARKS:** No review was done of the sterile diluent manufacture. The diluent provided for each vial of Menopur contains 2 mL of 0.9% Sodium Chloride. This sterile diluent is manufactured by Ξ ζ s (Vol. 2, p. 16) . Proposed labels for the diluent are provided on pages 17 and 18.

filename: N021663r1

9 Page(s) Withheld



 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

NDA 21-663

Menopur (menotropins for injection, USP)

Ferring Pharmaceuticals

Microbiology (efficacy)

MMW
10/29/04

N/A

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

James McVey
10/7/04 08:34:44 AM
MICROBIOLOGIST

David Hussong
10/12/04 03:30:31 PM
MICROBIOLOGIST