

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**103795/5123**

**Administrative/Correspondence**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Drugs Evaluation and Research

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Memorandum

Date: July 24, 2003

From: Karen D. Jones <sup>11/20</sup>  
Regulatory Project Manager  
Division of Application Review and Policy, HFM-588  
Office of Therapeutics Research and Review

To: STN BL 103795/5123 File

Subject: Biologic Therapeutic SBA equivalent for:

- Product: Etanercept, [Enbrel<sup>®</sup> is proprietary name]
- Manufacturer: Immunex Corporation.
- License Number 1132

**Indications and Usage**

The new indication approved for this BLA supplement is as follows: Enbrel<sup>®</sup> is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

**Dosage Form, Route of Administration, and Recommended Dosage**

- Enbrel<sup>®</sup> is supplied as a sterile, white, preservative-free lyophilized powder for parenteral administration after reconstitution with 1 mL of the supplied Bacteriostatic Water for Injection (BWFI), USP (containing 0.9% benzyl alcohol)
- Enbrel<sup>®</sup> is available in a multiple use vial containing 25 mg Etanercept, 40 mg mannitol, 10 mg sucrose and 1.2 mg tromethamine and is packaged in a carton containing four dose trays that each include one vial of Enbrel, one diluent syringe (1 mL Sterile Bacteriostatic water for Injection, USP, containing 0.9% benzyl alcohol, one 27 gauge ½ inch needle, one vial adapter, one plunger, and two alcohol swabs.
- Dosing: for adult patients with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis, 25 mg is given twice weekly as a subcutaneous injection 72-96 hours apart.

**Basis for Approval**

The following reviews, filed in the CDER/OTRR correspondence section of the license file for STN 103795/5123, comprise the SBA equivalent for this application:

Discipline	Reviewer Name	Date
Clinical (Safety and Efficacy)	William Tauber, M.D.	July 1, 2003
Statistical	Chao Wang, Ph.D.	April 30, 2003
Bioresearch Monitoring	Debra Bower	July 11, 2003

**APPEARS THIS WAY  
ON ORIGINAL**

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