

**CENTER FOR DRUG EVALUATION AND  
RESEARCH AND CENTER FOR BIOLOGICS  
EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**103950/0**

**ADMINISTRATIVE DOCUMENTS**

**MEMORANDUM**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

**DATE:** November 14, 2001  
**FROM:** Victoria Tyson-Medlock  
**TO:** License Number 1080  
**SUBJECT:** Summary Basis of Approval  
**BLA:** 103950/0  
**Manufacturer:** Amgen, Incorporated  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799

- **Drug License Name:** anakinra, Interleukin-1 receptor antagonist (IL-1Ra)
- **Drug Trade Name:** Kineret
- **Indications and Usage**

Interleukin-1 receptor antagonist (IL-1Ra), anakinra is indicated for the reduction in signs and symptoms of moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than Tumor Necrosis Factor (TNF) blocking agents.

- **Dosage Form, Route of Administration and Recommended Dosage**  
Anakinra is supplied in a single use preservative free, 1 mL prefilled glass syringes with 27 gauge needles. Each prefilled syringe contains 0.67 mL (100mg) of anakinra. Kineret is dispensed in packs containing 7 syringes. It is also available in a 4 x 7 syringe dispensing pack (28 syringes).

**Basis of Approval**

The basis of approval of anakinra for the treatment of rheumatoid arthritis is contained in the following appended documentation:

<b>Review Discipline</b>	<b>Reviewer</b>	<b>Date</b>	<b>Location</b>
Product-Final Drug	Ray Donnelly	11-06-01	CBER Correspondence
Clinical	Jeffrey Siegel	11-20-01	CBER Correspondence
Clin/Pharm	Martin Green	8-25-01	CBER Correspondence
Pharm/Tox	Anne Pilaro	11-13-01	CBER Correspondence
Biostatistics	Boguang Zhen	12-13-00	CBER Correspondence
BiMo	Debra Bower	10-16-00	CBER Correspondence
Facility	Reginald Neal	5-25-01	CBER Correspondence