DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-087

SEP 13 2005

Sandoz, Inc.
Attention: Beth Brannan
2555 W. Midway Blvd.
Broomfield, CO 80038

Dear Madam:

This is in reference to your abbreviated new drug application dated March 9, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Leflunomide Tablets, 10 mg and 20 mg.

Reference is also made to your amendments dated October 8, 2004; February 3, May 26, June 13, July 21, and September 8, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Leflunomide Tablets, 10 mg and 20 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Arava™ 10 mg and 20 mg Tablets of Aventis Pharmaceuticals, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The "Orange Book" also notes that Aventis Pharmaceuticals Inc. (Aventis) has exclusivities (I-395*PED and M-32*PED) expiring on December 13, 2006 and September 5, 2007, respectively, providing for the use of Arava® in the pediatric population. Section 11 of the Best Pharmaceuticals for Children Act (BPCA), signed into law in January 2002, allows certain portions of Aventis' labeling which is subject to pediatric exclusivity protection to be omitted from the labeling of products approved under Section 505(j) of the Act. The BCPA also permits the incorporation of language in the labeling of products approved under Section 505(j) that informs health care practitioners that Aventis' drug product has been approved for pediatric use. The agency has

determined that the final printed labeling you have submitted is in compliance with the BCPA with respect to pediatric use protected by exclusivity.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research