DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-905/S-012

Aventis Pharmaceuticals Inc.
Attention: Kerry Rothschild, JD
Director, Regulatory Affairs
200 Crossing Boulevard, PO Box 6890
Bridgewater, NJ 08807-0890

Dear Mr. Rothschild:

Please refer to your supplemental new drug application dated September 4, 2003, received September 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arava® (leflunomide) 10 mg, 20 mg and 100 mg tablets.

We acknowledge receipt of your submissions dated September 30, 2003 and March 4, 2004.

This supplemental new drug application provides for additional language to the **CLINICAL PHARMACOLOGY**, **CLINICAL STUDIES** and **ADVERSE REACTIONS** sections of the label.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted March 4, 2004). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 20-905/S-012**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at 301-827-2090.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, MD, PhD
Acting Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Deputy Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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

/s/

Brian Harvey
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