DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-905/S-015

Sanofi-Aventis
200 Crossing Boulevard
PO Box 6890
Bridgewater, NJ 08807-0890

Attention: Jay Kraker
Specialist, US Regulatory Affairs Marketed Products

Dear Mr. Kraker:

Please refer to your supplemental new drug application dated April 18, 2005, received April 19, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arava® (leflunomide tablets) 10 mg, 20 mg, 100 mg.

We acknowledge receipt of your submission dated April 18, 2005.

This "Changes Being Effected" supplemental new drug application provide for one editorial change in the **PRECAUTIONS – Hepatotoxicity** section of the label and the additional wording "vasculitis including cutaneous necrotizing vasculitis" in the **ADVERSE REACTIONS** postmarketing section section of the package insert.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert submitted April 18, 2005.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-905/S-015**. 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, call Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia and Rheumatology
Office of Drug Evaluation II

Enclosure

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

/s/

Bob Rappaport

10/19/2005 05:49:42 PM