DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-905/S-018

Sanofi-aventis
55 Corporate Drive
Bridgewater, NJ 08807

Attention: Colleen T. Donovan
Manager, US Regulatory Affairs Marketed Products

Dear Ms. Donovan:

Please refer to your supplemental new drug application dated October 16, 2008, October 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arava (leflunomide) oral tablets, 10mg, 20mg, 100mg.

We acknowledge receipt of your submission dated March 24, 2009.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS**: **General** 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 enclosed final printed labeling text (FPL) submitted on March 24, 2009.

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
Food and Drug Administration
Suite 12B05
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 Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Drugs
Office of New Drugs II
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/

Rigoberto Roca
4/3/2009 01:07:11 PM
for Bob Rappaport, M.D.