DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-905/S-016

Sanofi-Aventis, US, LLC
55 Corporate Drive
PO Box 5925
Bridgewater, NJ 08807

SUPPLEMENT APPROVAL

Attention: John Cook
US Regulatory Affairs Marketed Products

Dear Mr. Cook:

Please refer to your supplemental new drug application dated June 28, 2007, received June 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arava® (leflunomide) Tablets.

This "Changes Being Effected" supplemental new drug application provides for a revised WARNINGS section to include a subsection for Immunosuppression Potential/Bone Marrow Supression.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on June 28, 2007.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 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 Rappaport, M.D
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation 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/

Bob Rappaport

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