



NDA 14-399 / S-065

**SUPPLEMENT APPROVAL**

Sanofi-Aventis US, Inc.  
Attention: Jo Beth Crimmins  
Specialist, Heritage Product Support  
55 Corporate Drive, Mail Code 55A-430A  
Bridgewater, NJ 08807

Dear Ms. Crimmins:

Please refer to your supplemental new drug application dated and received October 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norpramin (desipramine HCl) Tablet.

This "Changes Being Effected" supplemental new drug application provides for several changes to the Norpramin labeling in the Warnings, Overdosage, and Dosage and Administration sections as requested in the Division's letter of September 11, 2009.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on October 14, 2009.

**LETTERS TO HEALTH CARE PROFESSIONALS**

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

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**REPORTING REQUIREMENTS**

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, email Renmeet Grewal, Pharm.D., RAC, Senior Regulatory Project Manager, at [Renmmet.Grewal@FDA.HHS.GOV](mailto:Renmmet.Grewal@FDA.HHS.GOV).

Sincerely,

*{See appended electronic signature page}*

Thomas Laughren, M.D.  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure  
Content of Labeling

| Application Type/Number | Submission Type/Number | Submitter Name           | Product Name          |
|-------------------------|------------------------|--------------------------|-----------------------|
| NDA-14399               | SUPPL-65               | SANOFI AVENTIS<br>US LLC | Desipramine Norpramin |

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

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/s/

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THOMAS P LAUGHREN  
10/26/2009