



NDA 016273/S-066

SUPPLEMENT APPROVAL

Sanofi-Aventis US LLC
Attention: Katherine Ng
Specialist, Base Business Product Support
55 Corporate Drive
Mail Stop 55C-205A
Bridgewater, NJ 08807-0912

Dear Ms. Ng:

Please refer to your Supplemental New Drug Application (sNDA) dated September 29, 2011, received September 29, 2011, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lasix (furosemide) 20 mg, 40 mg, and 80 mg tablets.

This “Changes Being Effected” supplemental new drug application provides for the following changes under ADVERSE REACTIONS;

New text has been added and the order has been revised.

From:

Dermatologic-Hypersensitivity Reactions

- | | |
|---------------------------|------------------------------|
| 1. exfoliative dermatitis | 6. urticaria |
| 2. bullous pemphigoid | 7. rash |
| 3. erythema multiforme | 8. pruritus |
| 4. purpura | 9. Stevens-Johnson Syndrome |
| 5. photosensitivity | 10. toxic epidermal necrosis |

To:

Dermatologic-Hypersensitivity Reactions

- | | |
|---|-----------------------|
| 1. toxic epidermal necrolysis | 7. bullous pemphigoid |
| 2. Stevens-Johnson Syndrome | 8. purpura |
| 3. erythema multiforme | 9. photosensitivity |
| 4. <u>drug rash with eosinophilia and systemic symptoms</u> | 10. rash |
| 5. <u>acute generalized exanthematous pustulosis</u> | 11. pruritus |
| 6. exfoliative dermatitis | 12. urticaria |

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

If you have any questions, please call Michael Monteleone, MS, RAC, Regulatory Project Manager, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

MARY R SOUTHWORTH
03/27/2012