



CONTENT OF LABELING

As soon as possible, but no later than one month from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, “**SPL for approved NDA 20-634/S-047, NDA 20-635/S-051, and NDA 21-721/S-015.**”

POSTMARKETING COMMITMENTS

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled studies to verify and describe clinical benefit. We remind you of your postmarketing study commitment (Subpart H Postmarketing Study Commitment) specified in your submissions dated May 5, 2008. This commitment is listed below:

1. To cooperate with U.S.-based public health agencies in evaluating data on the use of LEVAQUIN (levofloxacin) in a large U.S population for inhalational anthrax (post exposure) prophylaxis, should an exposure occur. This includes long-term safety data in pediatric patients from treatment greater than 14 days, if such data become available.

Final study reports should be submitted to these NDAs as supplemental applications. For administrative purposes, all submissions relating to this Phase 4 commitment must be clearly designated “**Subpart H Postmarketing Study Commitments.**”

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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NDA 21-721/S-015
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If you have any questions, call Rebecca D. Saville, Pharm.D., Regulatory Project Manager,
at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
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/

Renata Albrecht
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