DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-384/S-059

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Daniel Larkins
Manager, Regulatory Affairs
P. O. Box 1000, UG2C-50
North Wales, PA 19454-2505

Dear Mr. Larkins:

Please refer to your Supplemental New Drug Application (sNDA) dated March 10, 2011, received March 10, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NOROXIN (norfloxacin) Tablets.

This "Prior Approval" supplemental new drug application provides for revisions to the package insert to change information for *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control (QC) parameters for the *in vitro* susceptibility testing of organisms listed in the package insert.

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 labeling submitted March 10, 2011, with the following editorial changes (addition of underlined text):

1. Revise Table 2: Quality Control for Susceptibility Testing as follows:

Table 2: Quality Control for Susceptibility Testing		
Strains	MIC Range (µg/mL)	Zone Diameter (mm)
Enterococcus faecalis (ATCC 29212)	2 – 8	<u>Not applicable</u>
Escherichia coli (ATCC 25922)	0.03 – 0.12	28 – 35
P. aeruginosa (ATCC 27853)	1 – 4	22 – 29
Staphylococcus aureus (ATCC 29213)	0.5 – 2	<u>Not applicable</u>
Staphylococcus aureus (ATCC 25923)	<u>Not applicable</u>	17 – 28

2. In the REFERENCES section, at the end of both numerical bullets, the word "Villanova" should be replaced with the word 'Wayne".

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the submitted labeling (text for the package insert), with the editorial revisions requested above and the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the submitted labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 regarding this supplement, call Maureen Dillon-Parker, Chief, Project Management Staff at (301) 796-0706. For all other issues regarding this NDA, please contact Dr. Fariba Izadi, R.Ph., Pharm.D., Regulatory Health Project Manager, at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Sumati Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

SUMATHI NAMBIAR
05/27/2011