DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 12623/S-065

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Shai Srulovich, PharmD, RPh
Senior Manager, Worldwide Safety & Regulatory
235 East 42nd Street
New York, NY 10017

Dear Dr. Srulovich:

Please refer to your Supplemental New Drug Application (sNDA) dated September 9, 2011, received September 9, 2011, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flagyl (metronidazole) Tablets.

We acknowledge receipt of your amendments dated February 13 and June 28, 2013.

This "Prior Approval" supplemental new drug application provides for revisions to the package insert to harmonize labeling for all the systemic metronidazole products.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below and included in the attached package insert.

1. In the Microbiology section, Susceptibility Test Methods subsection, the sentence (b) (4) [redacted] is deleted (b) (4) [redacted]
2. In the Microbiology Section, Quality control subsection, the table headers have been revised to read as follows:

QC Strain	**Minimum Inhibitory Concentration** (mcg/mL)	
	Agar	**Broth**
Bacteroides fragilis ATCC 25285	0.25–1.0	0.25-2.0
Bacteroides thetaiotaomicron ATCC 29741	0.5–2.0	0.5-4.0

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 enclosed labeling test for package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed 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 that includes labeling changes 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, call Maureen Dillon Parker, Chief Project Staff, at (301)796-0706.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

SUMATHI NAMBIAR
08/16/2013