



NDA 012623/S-067
NDA 020334/S-010
NDA 020868/S-012

SUPPLEMENT APPROVALS

GD Searle, LLC
A subsidiary of Pfizer, Inc.
Attention: Michele Burtness
Senior Manager, Pfizer Essential Health Global Regulatory Affairs Brands
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Burtness:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 19, 2018, received January 19, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 012623/S-067	Flagyl (metronidazole) tablets, 250 mg & 500 mg
NDA 020334/S-010	Flagyl (metronidazole) capsules, 375 mg
NDA 020868/S-012	Flagyl (metronidazole) extended release tablets, 750 mg

These Prior Approval supplemental new drug applications provide for revisions to the **WARNINGS** section of the Prescribing Information regarding the risk of hepatotoxicity and death in patients with Cockayne Syndrome as requested in the Agency letter of December 7, 2017.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 text for the 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 include labeling changes for these NDAs, 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 Deborah Wang, PharmD, Regulatory Project Manager, at (301)796-9053.

Sincerely,

{See appended electronic signature page}

Joseph G. Toerner, MD, MPH
Deputy Director for Safety
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/

JOSEPH G TOERNER
04/03/2018