DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-558/S-069
NDA 50-643/S-022

SUPPLEMENT APPROVALS

Covis Injectables, S.à.r.l.
c/o Cardinal Health Regulatory Sciences
Attention: Todd Phillips, PharmD, RAC
US Agent
7400 West 110th Street
Overland Park, KS 66210

Dear Dr. Phillips:

Please refer to your Supplemental New Drug Applications (sNDA) dated January 23, 2009, received January 23, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 50-558/Zinacef (cefuroxime for injection) 0.75 g, 1.5 g, and 7.5 g
- NDA 50-643/Zinacef (cefuroxime injection) 0.75 g and 1.5 g

We acknowledge receipt of your amendments dated May 7, 2012, March 28, and September 22, 2014.

The March 28, 2014, submission constituted a complete response to our June 9, 2011, action letter.

These "Prior Approval" supplemental new drug applications provide for revisions to the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection of the package insert to update the *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control (QC) parameters.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended, and 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 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 via 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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved 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
09/25/2014