DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16-620/S-070
NDA 20-064/S-020

SUPPLEMENT APPROVAL

Alvogen IPCO S.a.r.l.
c/o Almatica Pharma, Inc., U. S. agent
Attention: Michelle Bucci
Director, Regulatory Affairs
9 Campus Drive
Parsippany, NJ 07054

Dear Ms. Bucci:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 8, 2010 (NDA 20-064/S-020), and September 28, 2010 (NDA 16-620/S-070) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 16-620/S-070 – Macrodantin (nitrofurantoin macrocrystals) 25, 50, 100 mg
NDA 20-064/S-020 - Macrobid Capsules (nitrofurantoin monohydrate/macrocrystals) 100 mg

These "Prior Approval" supplemental new drug applications provide for a review of the *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 these supplemental applications and agree that no changes are required in the *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control (QC) parameters sections of the labeling. However, we request that at the next printing the microbiology reference be updated to reflect the most recent versions of the Clinical and Laboratory Standards (CLSI) documents.

We note that the labels have been revised to reflect current labeling standards for antibacterial agents, however, no new content was added to the language of the current labels and no additions or deletions from the indication organisms were made.

Therefore, these supplements are approved, effective on the date of this letter, for use as recommended in the labels submitted September 8th and 28th, 2010, respectively.

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 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 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 these supplemental applications, 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 these supplements, call Maureen Dillon-Parker, Chief, Project Management Staff at (301) 796-0706. For all other issues regarding these NDAs, please contact Carmen DeBellas, R.Ph., Pharm.D., Senior Regulatory Project Manager, at (301) 796-1203.

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
06/06/2011