



NDA 50-162/S-090
NDA 50-441/S-061
NDA 50-639/S-022

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Beatrice Curran
Associate Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Curran:

Please refer to your Supplemental New Drug Applications (sNDAs) dated November 30, 2010, received November 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 50-162/S-090 Cleocin (clindamycin hydrochloride) Capsules
NDA 50-441/S-061 Cleocin Phosphate (clindamycin injection) Sterile Solution USP
NDA 50-639/S-022 Cleocin Phosphate (clindamycin injection in 5% dextrose) IV Sterile

These "Prior Approval" supplemental new drug applications provide 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 these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the labeling submitted November 30, 2010 [LAB-0040-6.0/Revised April 2010].

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 Effectuated" (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 Christopher Davi, M.S., Senior Regulatory Project Manager, at (301) 796-0702.

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
06/07/2011