DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 08922/S-018

APPROVAL LETTER

Medicis Pharmaceutical Corporation
Attention: Jennifer Mahilo
Associate Director, Regulatory Affairs
7720 N. Dobson Road
Scottsdale, AZ 85256

Dear Ms. Mahilo:

Please refer to your Supplemental New Drug Application (sNDA) dated February 21, 2013, received February 22, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Calcium Disodium Versenate.

We acknowledge receipt of your amendments dated March 21, 2013, April 17, 2013, May 8, 2013 and May 19, 2013.

This supplemental new drug application provides for a new manufacturing site - CP Pharmaceuticals ("Wockhardt"); and, a change in size of the container closure system from 2mL to 5mL and as a consequence a change in fill volume.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jewell Martin, Regulatory Project Manager, at (301) 796-2072.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief, Branch III
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

HASMUKH B PATEL
06/21/2013