



NDA 22-102/S-003

Fleming & Company, Pharmaceuticals
Attention: Phillip W. Dritsas, President
1733 Gilsinn Lane
Fenton, MO 63026

Dear Mr. Dritsas:

Please refer to your supplemental new drug application dated August 18, 2008, received August 19, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for CaloMist (cyanocobalamin, USP) Nasal Spray, 25 mcg/0.1 mL.

We acknowledge receipt of your submissions dated September 26, 2008 and March 16, 2009.

This "Changes Being Effected" supplemental new drug application provides for a reduction of the drug product bottle nominal fill volume from 18 mL to 10.7 mL.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We note that content of labeling in structured product labeling (SPL) format was included in your March 16, 2009, submission. We will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the final printed labeling (FPL) according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. The FPL must be identical to the enclosed labeling (immediate container and carton labels) submitted on August 18, 2008. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-102/S-003.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolism and Endocrinology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert, Patient Instruction Sheet, Immediate Container Label and Carton Label

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

/s/

Mary Parks
3/24/2009 04:30:30 PM