



NDA 20-687/S-013

Danco Laboratories, LLC

(b) (6), (b) (7)d

P.O. Box 4816
New York, NY 10185

Dear Mr. (b) (6), (b) (7)d

Please refer to your supplemental new drug application dated June 6, 2005 received June 7, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mifeprex[®] (mifepristone) 200mg Tablets.

This supplemental new drug application provides for updated information to the WARNINGS section of the labeling.

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

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the 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. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-687/S-013.**" Approval of this submission by FDA is not required before the labeling is used.

When 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, HFD-410
FDA
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 (b)(6), (b)(7)d -----

Sincerely,

{See appended electronic signature page}
(b)(6), (b)(7)d

Enclosure

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

/s/
(b)(6), (b)(7)d-----
