



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-687

Danco Laboratories, LLC
Attention: _____
President and Chief Executive Officer
P.O. Box 4816
New York, NY 10185

Dear _____

Please refer to your new drug application (NDA) submitted September 21, 2004, received September 22, 2004, under section 505(b) of the Federal Food, Drugs, and Cosmetics Act for MIFEPREX[®] (mifepristone) Tablets.

We also acknowledge receipt of your submissions dated October 20, November 1, 8, 9, and 12, 2004.

This supplemental new drug application provides for changes to the physician insert, Medication Guide, and Patient Agreement Form of the label.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, the Medication Guide, the Patient Agreement Form, and the Prescriber's Agreement Form).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-687/S-010." Approval of this submission by FDA is not required before the labeling is used.

We request that you submit a copy of the "Dear Health Care Professional" and "Dear Emergency Room Director" letters communicating important information about this drug product 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

Sincerely,

{See appended electronic signature page}

Center for Drug Evaluation and Research

Enclosure

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

/s/

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