DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-687/S-015

Danco Laboratories, LLC
(b) (6)

P.O. Box 4816
New York, NY 10185

Dear (b) (6):

Please refer to your supplemental new drug application dated October 23, 2008, received October 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MIFEPREX (mifepristone) Tablets.

We also refer to your amendment dated April 22, 2009.

This supplemental new drug application provides for the minor revisions to the Physician Insert (PI) and Medication Guide. Deletions are designated by ~~strikethrough~~ and insertions by underline.

In the **WARNINGS** section of the PI, under **2. Infection and Sepsis**, the second paragraph has been modified to read as follows:

2. Infection and Sepsis

A high index of suspicion is needed to rule out sepsis (from e.g. *Clostridium sordellii*) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. Most of ~~T~~these deaths occurred in women who used vaginally administered misoprostol. ~~, but n~~ No causal relationship between Mifeprex and ~~vaginal~~ misoprostol use and an increased risk of infection or death has been established. *Clostridium sordellii* infections have also been reported very rarely following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

In the **Postmarketing Experience** subsection of the **ADVERSE REACTIONS** section of the PI, the second paragraph has been modified to read as follows:

Postmarketing Experience

Allergic reaction (including rash, hives, itching), hypotension (including orthostatic), light-headedness, loss of consciousness, post-abortal infection (including endomyometritis, parametritis, pelvic infection), ruptured ectopic pregnancy, shortness of breath, ~~and~~ tachycardia (including racing pulse, heart palpitations, heart pounding), and hematometra.

The subsection "**What symptoms should I be concerned with?**" within the section "**What is the most important information I should know about Mifeprex?**" of the Medication Guide has been modified to read as follows:

> **What symptoms should I be concerned with?** Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Prompt medical attention is needed in these circumstances. Serious infection has resulted in death in a very small number of cases; in most of these cases ~~which~~ misoprostol was used in the vagina. There is no information that ~~vaginal~~ use of Mifeprex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your provider. Your provider's telephone number is _____.

We have completed our review of this application, as amended, and the application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on April 22, 2009.

Within 14 days of the date of this letter, submit content of labeling [21CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 14.80 and 314.81).

If you have any questions, call (b) (6).

Sincerely,

{See appended electronic signature page}

(b) (6)

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/

(b) (6)

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