

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**020687Orig1s020**

**STATISTICAL REVIEW(S)**



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research

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# STATISTICAL REVIEW AND EVALUATION

## CLINICAL STUDIES

**NDA/Serial Number:** 020687/S-020  
**Drug Name:** Mifeprex (mifepristone)  
**Indication:** Medical termination of pregnancy through (b) (4) days gestation  
**Applicant:** Danco Laboratories, LLC  
**Date(s):** Submission Date: 5/29/2015  
PDUFA Due Date: 3/29/2016  
**Review Priority:** Standard

(b) (6) **Division:** (b) (6)

**Statistical Reviewer:** (b) (6)

**Concurring Reviewers:** (b) (6)

**Medical Division:** (b) (6)

**Clinical Team:** (b) (6)

**Project Manager:** (b) (6)

**Keywords:** NDA review, clinical studies

## BACKGROUND

Mifeprex (mifepristone) is a progestin antagonist approved by the FDA on September 28, 2000, indicated for the medical termination of intrauterine pregnancy through 49 days gestation. Mifepristone 600 mg orally is administered on day 1, followed by misoprostol 400 mcg orally 48 hours later.

Danco Laboratories, LLC submitted an efficacy supplement on May 28, 2015, proposing labeling revisions for Mifeprex (mifepristone). These labeling revisions reflect established medical practice in regards to medical termination of pregnancy, and include changes to the eligible gestation age and (b) (4) dosing regimen, and are further described below.

**Current indication:** medical termination of pregnancy through 49 days gestation

**Current dosing/administration regimen:** 600 mg of mifepristone orally on day 1, followed by 400 mcg of misoprostol orally on day 3 (for pregnancies up to 49 days gestation)

**Proposed (b) (4) indication:** medical termination of pregnancy through (b) (4) days gestation

**Proposed (b) (4) dosing/administration regimen:** 200 mg of mifepristone orally on day 1, followed by 800 mcg of misoprostol buccally on day 2 or 3 (additional option for pregnancies up to (b) (4) days gestation).

## CONCLUSION

There was no new efficacy data submitted in support of this supplement. Therefore, no statistical review was necessary.

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