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For Immediate Release: July 18, 2005 **Contact: Chrissy Faessen (202) 220-3763**

New York, NY – Danco Laboratories announced today that it is modifying the labeling for Mifeprex® to include updated safety information.

Mifeprex® has been available in the U.S. for almost 5 years, and more than 460,000 women in this country have chosen it for early abortion since FDA approval in September 2000. During that time period, Danco has received reports of five deaths from serious bacterial infection and sepsis following treatment with Mifeprex® and misoprostol. "All of these cases had atypical presentations of infection, and in the first three cases, the bacteria were identified as a very rare anaerobic, gram-positive, spore forming species known as Clostridium *sordellii*," said Richard Hausknecht, M.D., Medical Director, Danco Labs. One of these cases occurred during a clinical trial in Canada in 2001. The other four cases were reported from California – two in late 2003, one in early 2004, and a recent one in mid 2005. No causal relationship between these events and the use of Mifeprex® and misoprostol has been established.

Childbirth, menstruation and abortion, whether spontaneous, surgical or medical, all create conditions that can result in serious and sometimes fatal infection, and there is no evidence that Mifeprex® and misoprostol present a special risk of infection[1]. Clostridium *sordellii* is a common soil and enteric bacterium that has presented in a very small number of obstetric and gynecologic cases, including following childbirth (vaginal delivery and caesarian section), medical abortion, and in other gynecologic and non-gynecologic conditions.[2]

Women who are undergoing a medical abortion with the Mifeprex® and misoprostol regimen should contact their provider or an emergency room right away if they experience abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhea), with or without fever, more than 24 hours after taking misoprostol.

"Danco is committed to providing updated safety information about this early option for women. We will be sending a Dear Doctor Letter soon to all providers of Mifeprex®, as well as to all emergency room directors, to ensure that they are aware of this new information," said Cynthia Summers, Dr.P.H., Director of Marketing and Public Affairs, Danco Labs. "Danco is working with the FDA to update the Mifeprex® labeling, Medication Guide and Patient Agreement with this information."

Danco Laboratories, LLC exclusively markets Mifeprex® (mifepristone) in the United States.

[1]Grimes, D. Risks of mifepristone abortion in context. *Contraception*, 2005; 71: 161.
[2]e.g. Bitti, A. et al. A fatal postpartum Clostridium *sordellii* associated toxic shock syndrome. *Journal of Clinical Pathology*, 1997; 50:259-260. McGregor, J.A. et al., Maternal deaths associated with Clostridium *sordellii* infection. *American Journal of Obstetrics and Gynecology*, 1989; 161(4): 987-995. Rorbye, C. et al. Postpartum Clostridium *sordellii* infection associated with fatal toxic shock syndrome. *Acta Obstet Gynecol Scand*, 2000; 79(12): 1134-1135.