POPULATION COUNCIL/DANCO LABORATORIES, LLC

ANNUAL REPORT FOR MIFEPRISTONE TABLETS, 200 mg

NDA # 20-687

TIME PERIOD COVERED: SEPTEMBER 28, 2000 –SEPTEMBER 27, 2001

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9(a) SUMMARY OF SIGNIFICANT NEW INFORMATION

The reporting period for the first year since approval included approximately ten and a half months during which Mifeprex was available to health care providers and their patients.

During that time, thirty-two adverse events were reported to Danco and reported by Danco to FDA in periodic reports. Of the 32 reported adverse events, two were 15-day reports (the others were not serious and/or not unexpected). One of the 15-day reports was reported as "hemorrhage due to a ruptured ectopic pregnancy and death." The other was reported as "post abortal parametritis/endometritis, adult respiratory distress syndrome and bilateral pneumonia." This latter 15-day report and one case where fever was reported represent the total reports on the marketed drug suggesting infection. In addition, one infection was reported in the Population Council's 200 mg mifepristone study and one death due to clostridium sordelli infection was reported in the Canadian study. A labeling supplement submitted on November 14, 2001 proposed new text on bacterial infection for inclusion in the prescribing information.

The approval letter for this product waived the pediatric requirement, so nothing on that subject is reported.

9(b) DISTRIBUTION DATA

During the reporting period of September 28, 2000 to September 27, 2001, a total of [redacted] batches were released for distribution.

The NDC number for Mifepristone Tablets, 200 mg is 64875-001-03. A summary of the commercial distribution data for the reporting period is tabulated below.

DISTRIBUTION DATA FOR MIFEPRISTONE TABLETS, 200 mg

NDC 64875-001-03	Number of packages (3 tablets/package)
Number of patient packs shipped	[redacted]
Number of patient packs returned (short dating)	
Net number in commerce	

The distribution system agreed with the FDA at approval remains in place.