November 21, 2003

Dockets Management Branch
Food & Drug Administration
Dept. of Health & Human Services
Room 10-61
5630 Fishers Lane
Rockville, MD 20857

RE: Docket 01P-0075 ("Switch Status of Emergency Contraceptives from Rx to OTC")

Dear Commissioner:

I strongly oppose the reclassification of “emergency contraceptives” as an over the counter drug.

Many women, expressing their moral or religious convictions, would choose not to use these drugs should relevant medical information regarding the status of their pregnancy not be withheld from them.

I recommend that both doctors and pharmacists be required to obtain written consent from the patient or the patient’s parent and/or legal guardian, before prescribing/dispensing these products. Emergency contraceptives should be available by prescription only.

Essentially the consent form would include such things as: if the sperm has already fertilized the egg, and a living human embryo now exists, then taking this medication after this happens may prevent the human embryo from implanting in the uterine wall, thus resulting in the human embryo to be expelled from the body; the long-term effects of this regimen have not been established; likewise the effects on the development of an unborn child have not yet been determined.

Women who find out that this information was concealed from them and the drug regimen violated their religious conscience, may feel subsequent depression, remorse, guilt or religious censor.

Denying the proper disclosure of information, that is reasonably relevant to a woman’s decision, is a grave violation of patient’s rights. Women have a right to know.

Emergency contraceptives should be available by a prescription only!!!

Sincerely,

[Signature]

[Handwritten Signature]
Dear Commissioner:

RE: Docket 01P-0075 ("Switch Status of Emergency Contraceptives from Rx to OTC")

I strongly oppose the reclassification of "emergency contraceptives" as an over the counter drug.

Many women, expressing their moral or religious convictions, would choose not to use these drugs. Certain relevant medical information is not being disclosed to them, but rather concealed from them. Pertinent information is being withheld from women that would be relevant to their decision in using this drug regimen.

I recommend that both doctors and pharmacists be required to obtain written consent from the patient before prescribing/dispensing these products. Emergency contraceptives should be available by prescription only.

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Sincerely,

Mary Beth Mcchl
November 30, 2003

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