F.D.A. Adds Hurdles in Approval of Abortion Pill

By SHERYL GAY STOLBERG

WASHINGTON, June 7 — The long-running effort to bring the French abortion pill to women in this country has encountered yet another obstacle: a suggestion by the Food and Drug Administration that it may place tight restrictions on how the drug, RU-486, is distributed and who can prescribe it.

Typically, once a drug is approved, any doctor can prescribe it for any purpose. But people familiar with negotiations between the F.D.A. and the sponsor of RU-486, which is also known as mifepristone, say the agency is considering taking several unusual steps, including restricting prescribing privileges to doctors who perform surgical abortions.

That would effectively eliminate what advocates of abortion rights see as mifepristone's main advantage, moving the procedure out of potentially high-profile clinics and into the private offices of gynecologists, family practitioners and other doctors.

"It kills the drug if it can't be used by primary care providers," said Dr. Eric Schaff, a professor of family medicine at the University of Rochester who has run clinical trials of RU-486. "The whole idea of mifepristone was to increase access."

Indeed, that is mifepristone's potential. A study released today by the Kaiser Family Foundation found that 1 in 4 gynecologists who do not perform abortions would prescribe mifepristone if it was approved by the F.D.A But the study also found that doctors would have second thoughts if they were required to undergo training to use the drug, another condition the F.D.A. is considering.

Officials of the food and drug agency refused to comment on the negotiations, as did the Population Council, a nonprofit research group that holds the rights to market mifepristone in the United States.

Heather O'Neill, a spokeswoman for the Danco Group, the investors who have licensed those rights and are arranging for the drug to be manufactured and distributed in this country, said, "The agency's initial approach is more restrictive than we had envisioned for a drug that has been used safely by so many women."

But Ms. O'Neill would not elaborate, beyond saying, "We are in the very early stages of a delicate negotiation process with the F.D.A."

Studies show that when taken with misoprostol, an already approved medication, mifepristone causes abortion — in essence, a miscarriage — in more than 95 percent of women who are no more than 49 days pregnant. After years of controversy, the F.D.A. announced in 1996 that mifepristone was safe and effective for use in this country.

But the final approval process has been fraught with complications, in part because the drug's sponsors had trouble finding a manufacturer. That issue has been settled (the manufacturer's identity remains undisclosed), and in February, the F.D.A. notified the Danco Group that it would give final approval to RU-486 if certain labeling and manufacturing issues could be resolved.

The agency has until Sept. 30 to either approve the drug, reject it or call for a further delay. Negotiations were proceeding apace when, at a Population Council meeting last Friday, officials from the Danco Group announced that they had just received a new set of requirements from the F.D.A. Dr. Michael Burnhill, medical affairs vice president for Planned Parenthood of America, said the list had caught Danco officials by surprise.

"They thought all the F.D.A. requirements had been dropped on the table in February," he said.

In addition to requiring that only abortion practitioners prescribe mifepristone, Dr. Burnhill said, the F.D.A. is demanding that prescribing doctors be trained in mifepristone's use, be trained in reading ultrasound scans, and maintain admitting privileges at hospitals with emergency facilities no more than an hour from their offices, in case women experience complications.

Dr. Burnhill said doctors would have to register with the drug's distributor "so that the distributor would not be supplying the product to every Tom, Dick and Harry." The proposal also contained a subtle, but important, wording change: because the word "physician" was used, not "provider," nurse-practitioners would be unable to prescribe mifepristone.

Though rare, similar requirements have been imposed on other drugs, including thalidomide and certain narcotics used to relieve pain in cancer patients.

Some abortion rights advocates and others who favor approval of RU-486 fear that the requirements would lead to creation of a national list of mifepristone providers, giving abortion opponents an opportunity to single out those doctors.

Others say the F.D.A. is succumbing to political pressure and treating women unfairly.

"To encumber a drug like this is extremely unusual for the F.D.A.," said Dr. Wendy Chavkin, a professor of public health at Columbia University. "We have Viagra that went out in widespread fashion even though there was some suggestion that it might cause serious cardiovascular events. In contrast, this is a highly studied drug where the safety and efficacy have been demonstrated. That indicates how the political climate is really interfering in the science."