DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 9 1992

Dear Ms. Millican:

This is in reply to your letter of February 26, 1992, in which you asked the FDA to comment on the use of Lupron (leuprolide acetate), in the treatment of endometriosis and in an in vitro fertilization program.

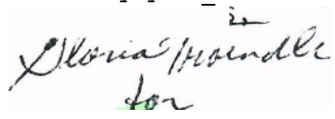
Lupron has been approved for the treatment of prostate cancer in two different dosage forms, April 1985 as a daily injection and January 1989 for depot (7.5 mg) administration. Approval of Lupron in its depot (3.75 mg) form for the management of endometriosis was granted in October 1990. These are the only approved indications for the use of the drug as of this date.

Please find enclosed a copy of the labeling for the 3.75 mg depot strength of Lupron. This package insert should provide you with an overview of the drug for the management of endometriosis, as well as the side effects, such as insomnia and hot flushes, that may occur in using the product.

Due to government regulation, I am unable to acknowledge or discuss any current or projected research which involves the use of Lupron in the treatment of any other disease or condition other than those for which it is approved. This information may be available to you through either your public library or a medical library which has access to a MedLine-type database.

I hope that this information is helpful to you.

Sincerely your_



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Enclosures