January 29, 2000

Food and Drug Administration 5600
Fishers Lane Rockville, MD 20857

Dear Sirs/Madam:

I am writing to inquire about the FDA's labeling of Lupron (leuprolide acetate). Since the NIH and OSHA classify Lupron as a "hazardous drug" - there are several questions which I'm hoping you can answer:

1. Why is there no labeling from the FDA regarding Lupron's "hazardous drug" status?

2. Why are there no special instructions in the package insert for Lupron regarding the protective gear healthcare workers are advised (by NIH and OSHA) to use when "handling" Lupron?

3. Since there is no such warning in Lupron's package insert, by what means are healthcare workers to learn that when handling the hazardous drug Lupron, protective gear (i.e. mask, gown, two pairs of chemotherapy gloves) is advised?

4. Since the NIH and OSHA advise healthcare workers to not only use special protective gear when "handling" Lupron but also to avoid any contact with Lupron for at least 3 months if the healthcare worker is planning to conceive or father a child - how is it that Lupron is routinely injected into women undergoing fertility treatment?

5. Where the FDA claims no jurisdiction over physician prescription practices, and therefore has never answered question #4 in a substantive way - who is to protect the infertile consumer from injecting Lupron, a hazardous drug, in the fertility clinic setting?

If it should be necessary to request this information under the Freedom of Information Act, then please consider this letter as sent under this Act.

Thank you for your time and attention to this matter.

Sincerely,

Lynne Millican