DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Services

Food and Drug Administration
Rockville, MD 20857

March 24, 2000

Dear Ms. Millican:

This is in response to your letter dated January 29, 2000, to the Food and Drug Administration (FDA) requesting information about Lupron (leuprolide acetate). Your letter was forwarded to my office in the Center for Drug Evaluation and Research (CDER) for a reply.

The FDA does not have a classification system, such as the one used by the Occupational Safety and Health Administration (OSHA), that defines drug products as hazardous for health care workers whose occupational duties place them at risk for exposure. Establishing and/or maintaining such a classification system is out side of the regulatory responsibility of the PDA. This classification system falls under the purview of OSHA You may wish to contact OSHA directly if you have additional questions regarding the hazardous classification of leuprolide.

It is the responsibility of individual employers to develop, implement, and maintain at the workplace a written hazard communication program for employees handling or otherwise exposed to chemicals, including drugs, that may represent a health hazard. The written program should include a list of the covered hazardous drugs known to be present in the workplace.

The FDA is responsible for ensuring that drug products are safe and effective for use as directed in the labeling. The labeling of prescription drugs, such as Lupron, is reviewed and approved by the FDA prior to marketing. This labeling is a summary of the essential scientific and medical information about the drug and reflects the results obtained from clinical trials of the drug. This information alerts health care workers and consumers to the risks and benefits of the product.

Thus, the FDA-approved product labeling, including the patient package insert, reports drug characteristics that may meet the defining criteria for hazardous drugs. OSHA places the responsibility for developing and maintaining a Hazardous Communication Program on each health care employer and requires them to make an assessment and inform their employees about whether a particular drug or formulation meets the criteria which define hazardous drugs.

The FDA has approved leuprolide acetate in different dosages and for different indications. Lupron Depot Injection (leuprolide acetate), manufactured by Tap Holdings, was first approved

by the Food and Drug Administration on October 22, 1990, for the treatment of endometriosis. Lupron Depot Pediatric Kit was approved on April 16, 1993 for treatment of children with central precocious puberty; Lupron Depot Injection was approved on March 30, 1995 for the treatment of leiomyoma uteri (uterine fibroids); Lupron Depot Three-Month Injection was approved on December 22, 1995 for the palliative treatment of advanced prostatic cancer; and Lupron Depot Three-Month Injection was approved on March 7, 1997, for the treatment of endometriosis.

Once approved, a drug product may be prescribed by a licensed physician for any use that, based on the physicians professional opinion, is deemed to be appropriate. The use of prescription drug products for indications other than those approved by the FDA (off-label use) is considered the practice of medicine by the PDA. The Federal food, Drug , and Cosmetic Act does not authorize the FDA to regulate the practice of medicine. Therefore, I am unable to comment on the use of any drug product outside of the approved indications. I suggest that you speak with your physician regarding your concerns. Should you have complaints about a physician, you may wish to contact your state medical board.

The premise of prescription drugs is that they require a "learned intermediary", such as a licensed physician, to give guidance to the patient on the safe and proper use of the medicines, and of any risks and precautions regarding the particular drug in question. Selection of specific drug products or treatment regimens for particular patients are decisions to be made between the patient and a physician who is familiar with the individuals' current health status and past medical history. We believe that consumers should request complete information about any drugs that they, or their family members, are taking so that they can make informed decisions regarding their medical treatment and care. State licensing boards, both medical and pharmacy, however, set the standards of practice for the professions in prescribing and dispensing products that we have allowed on the market. You may wish to contact your state medical board to discuss you concerns regarding patient protection and counseling, and the dispensing of drug information to patients.

I hope this information is helpful.

Sincerely,

Diana Hernandez
Consumer Safety Officer
Drug Information Branch, HFD-210
Office of Training and Communications
Center for Drug Evaluation and Research