

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 23, 1994

Dear Ms. Millican:

This is in reply to your letter dated October 4, 1994.

I am enclosing a copy of my response dated May 3, 1994, which answers many of your same questions.

Please note the answers to questions three and four of my previous correspondence. These statements are still accurate.

You may wish to obtain a copy of the Summary Basis of Approval for Lupron. This is the approval letter, labeling, chemist review, pharmacologist review, medical officer review, as well as all other reviews for this product. Because there may be a charge incurred, we are unable to forward your request. You can access the information in our system by writing the Freedom of Information Staff, HFI-35, at the letterhead address.

Sincerely yours,



Diane F. Walker
Consumer Safety Officer
CDER Executive Secretariat Staff (HFD-8)
Center for Drug Evaluation and Research

Enclosure