

PAMELA BALSE  
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01936-0308

DOCKETS MANAGEMENT BRANCH (HFA-305)  
Food and Drug Administration  
5630 FISHERS LANE Rm. 1061  
ROCKVILLE, MD, 20857 JUL 30 1999  
RE: DOCKET NO. 98N-1265

TO THE FDA:

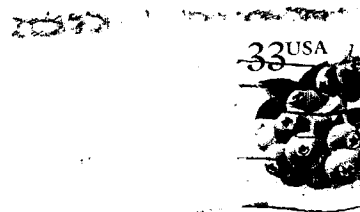
I SEND THIS LETTER AS A CONSUMER OF HEALTH CARE SERVICES TO REGISTER MY CONCERN AND DISAPPROVAL OF THE MEMORANDUM OF UNDERSTANDING published by the FDA ON JAN. 21, 1999. IN ITS PRESENT FORM THE MOU AS WELL AS THE COMPOUNDING SECTION 503A OF THE MODERNIZATION ACT, SEVERELY RESTRICTS THE RIGHTS OF THE PHYSICIAN AND PATIENTS TO OBTAIN HEALTH CARE PRODUCTS FROM THE PROVIDER OF THEIR CHOICE. IT ALSO INFRINGES ON THE RIGHTS OF COMPOUNDING PHARMACISTS TO SERVE THE PUBLIC'S MEDICAL NEEDS. AS A HEALTH CARE CONSUMER THERE SHOULD BE NO RESTRICTIONS TO THE DELIVERY OF COMPOUNDED MEDICATION PRESCRIBED FOR ME REGARDLESS OF WHERE I LIVE OR TRAVEL. THE MOU MUST BE AMENDED!

THE MEDICATION I AM CURRENTLY TAKING WAS PRESCRIBED TO ME BY MY PHYSICIAN WHO IS ON THE STAFF OF MASSACHUSETTS GENERAL HOSPITAL IS ALSO ON THE FACULTY OF HARVARD MEDICAL SCHOOL, I TRUST HER JUDGMENT! THE MEDICATION IS COMPOUNDED BY A WELL KNOWN AND REPUTABLE COMPOUNDING PHARMACY. THE MEDICINE HAS BEEN EFFECTIVE WITHOUT THE UNNECESSARY SIDE EFFECTS I HAD EXPERIENCED WHILE ON SYNTHETIC PROGESTINS (PROVERA) WHICH I WILL NO LONGER TAKE UNDER ANY CIRCUMSTANCES. I FEEL MY HEALTH WILL BE AT RISK IF I CAN NO LONGER OBTAIN THIS MEDICATION, NATURAL PROGESTERONE, WHICH IS COMPOUNDED BY THE WOMEN'S INTERNATIONAL PHARMACY, MADISON, WI.

SINCERELY, PAMELA BALSE  
P.O. Box 308,  
HAMILTON, MA  
01936-0308

98N-1265

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DUCKETS MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION,  
5630 FISHERS LN Rm. 1061  
ROCKVILLE MD 20857-0003

