May 25, 1998

To Whom It Concerns,

8408 '99 JUN -1 AM 10:40

I oppose the Draft Memorandum being proposed by the FDA. In particular, I object to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Eight years ago I had an emergency hysterectomy. I have done aerobics since college and am a healthy women, in very good shape. I was placed on hormone therapy and began suffering many side effects. My doctor tried different brands and types of hormones - all synthetic and from large pharmacy companies. I could not live sanely with the side effects and chose not to take any hormones. After 2 years, the effects of having almost no hormones in my body began to cause problems.

Finally, I had blood tests done and had hormones compounded especially for me and my needs. These hormones had to be ordered from a company outside of my state. The hormones are natural, not synthetic. I have a medical history of reacting to drugs and chemicals. These natural hormones have made a drastic difference in my life and

98N-1265

C2985

health. I know many other women are in the same position that I found myself in.

Please do not take away my health and my ability to choose what is best for me. I know what is best by the way my body reacts to drugs and knowing when I feel healthy. Large companies make a one-size fits all type of drug. One size does not fit all - in clothes or drugs.

For my health and safety, I need the choices that special compounding of drugs offers. Please be responsible and accountable to people with health needs, not large pharmacy companies, or easy one drug for all solutions - Because the only health solution is choice for each individual is different.

Sincerely,

Nikki L. Blaha

Nikki L. Blaha

Nikki L. Blaha
7468 Berkshire Pines Dr.
Naples, FL 34104

FT. MYERS FL 33913
PM
25 MAY
1999

USA H
First-Class Rate

Dockets Management Branch (HFA-305)
FDA - Docket #98N-1265
Food and Drug Administration
5630 Fishers LN
Room
Room

20837/0003