DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

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 as published by the FDA on January 21, 1999.
In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act of 1997, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the publics medical needs. As a healthcare 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 FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!
Comments: I cannot take synthetic progestins due to their serious side effects. I am able to take micronized progesterone to control my heavy and abnormal periods that occur at least every 14 days without HRT. PLEASE amend the MOU. My health depends on the ability to compound drugs.

Signed: Carole Kelley

Rainier, Oregon 97048

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