6-2-1999

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TO THE FDA:

RE: DOCKET NO. 98N-1265

I SEND THIS LETTER AS A CONSUMER OF HEALTHCARE 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 COMPOUNDING SECTION 503A OF THE MODERNIZATION ACT, SEVERLY 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 PUBLIC'S MEDICAL NEEDS. AS A HEALTHCARE CONSUMER, THERE SHOULD BE NO RESTRICTIONS TO THE DELIVERY OF A COMPOUNDED MEDICATION PRESCRIBED FOR ME, REGARDLESS OF WHERE I LIVE OR MAY TRAVEL. THE MOU MUST BE AMENDED!

THE F.D.A. IS AN AGENCY OF THE U.S. GOVERNMENT THAT PURPORTS TO BE THE "WATCHDOG" FOR

98N-1265

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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.

Ruth E. Lewis
Arizona

Ruth E. Lewis
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PM
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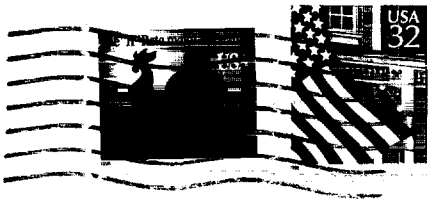
1999



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