The Director
Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20857-0003

5721 '99 JUN 30 P1:55

Re Docket No. 98N-1265

Dear Director,

As the MOU of 1/21/91 and the Compounding Section 503A in its restriction of compounding pharmacists to serve the public (both in making "alternative" medications & giving valuable counseling (e.g., pharmaceutical) goes against the grain of free enterprise. In its present form (amended), the limits on "interstate" commerce in these suspect medications seems entirely too heavy handed for our democratic country.

Maybe, FDA could consider

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setting pharmacy standards for organics — maybe you already do. Rather than restrict the spirit of free enterprise, some well advised suggestions to this necessary alternative "industry" could far more beneficial to all concerned (even the PMA could benefit - no need to pay lawyers to argue against these compounding pharmacists).

If it's public safety you'd like to protect, the compounding pharmacists may indeed serve to further your cause by enabling people to avoid drugs that, with many years of use, can indeed be toxic (e.g., ibuprofen - liver toxicity). Please consider amending the MOU to preserve this option for many who need this alternative to

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chronic pain and life threatening diseases that are not helped by main-stream pharmaceuticals!

Thank you for your attention.

Sincerely yours,

J B Silberman
Falls Church, VA
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