

Lawton Chiles
Governor



James T. Howell, M.D., M.P.H.
Secretary

October 19, 1998

Elizabeth E. Hiner, RPh
Assistant to the Director
Division of Federal-State Relations, HFC 150
Food and Drug Administration
Rockville, MD 20857

Dear Ms. Hiner:

The Florida Board of Pharmacy respectfully submits the enclosed proposed *Memorandum of Understanding* for consideration by the Food and Drug Administration. It is the desire of the Florida Board of Pharmacy to address this issue before the effective date of the federal compounding legislation.

The Board hopes that this proposal will be acceptable to the agency, but it will obviously consider your revisions or alternatives.

If you have any questions, or if I may be of any assistance, please let me know. I may be reached directly at 850-488-6526.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Taylor".

John D. Taylor, RPh
Executive Director
Florida Board of Pharmacy

/jdt

CC: Carmen Catizone
Robert Hoye

Proposed Memorandum of Understanding

Between

The Florida Board of Pharmacy

And

The Food and Drug Administration

I. INTRODUCTION

Pursuant to Section 127, "Pharmacy Compounding" of the Food and Drug Modernization Act of 1997, the Florida Board of Pharmacy has developed this memorandum of understanding to address specific issues related to compounded drugs. The purpose of this memorandum of understanding is to provide specific guidelines on the dispensing of compounded drug products.

II. INVESTIGATION OF COMPLAINTS OF COMPOUNDED DRUGS SENT OUT-OF-STATE

The board of pharmacy in the state in which the compounding pharmacy is located will investigate complaints about compounded drugs that are shipped out of state. That board may obtain the assistance of the board of pharmacy that is located in the state where the compounded drug was shipped.

III. INORDINATE DISTRIBUTION OF COMPOUNDED DRUGS OUT-OF-STATE

A pharmacy may dispense compounded drugs interstate, provided that the pharmacy notifies the state board of pharmacy with which it is registered and provides additional information that may be required by the board of pharmacy. The Florida Board of Pharmacy shall develop procedures to implement this notification requirement. This notification shall not be in lieu of any registration or licensure requirements that may be applicable to the pharmacy in the state into which it ships compounded medication.