



**International Academy
of Compounding Pharmacists**

P.O. Box 1365
Sugar Land, Texas 77487

281/933-8400 voice
281/495-0602 fax
1-800-927-4227

www.iacprx.org
iacinfo@iacprx.org

August 23, 2000

Ms. Jane A. Axelrad
Associate Director For Policy
Center for Drug Evaluation and Research
Food and Drug Administration (HFD-005)
Woodmont Office Complex 2
1451 Rockville Pike
Rockville, MD 20852

Dear Jane:

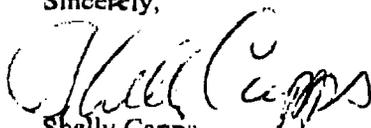
I'm glad we finally spoke before I left the office. While IACP is certainly open to inventive solutions to ensure the continuance of current compounded medications, such as 4-AP, I believe FDA's proposed approach will be cumbersome and unworkable.

It was our understanding that the Committee recommended that if IACP provided stability data, formulations and the approximate number of patients on 4-AP, this medication would be put on the positive list. Your suggested approach of using an IND would restrict the distribution and require unprecedented procedures inconsistent with the pharmacy legislation. Moreover, the positive list mechanism does not involve INDs. Given the significant paperwork constraints associated with INDs, I don't think compounding pharmacists would support such an approach. Therefore, I am unwilling to authorize an expensive stability study until a viable, clearly delineated solution is agreed upon.

I am hopeful that between now and our conversation scheduled for the first week in September, this project can be more clearly defined.

Thank you for discussing this issue, and for notifying me that the comment period has been extended. I look forward to talking with you further in September.

Sincerely,


Shelly Capps
Executive Director

98D-0272

C13