



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 14 2000

Food and Drug Administration
Rockville MD 20857

Shelly Capps
Executive Director
International Academy of Compounding Pharmacists
P.O. Box 1365
Sugar Land, TX 77487

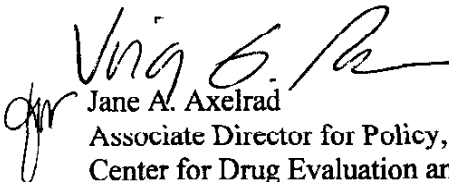
Dear Ms. Capps:

This letter responds to your July 21, 2000, letter to the Food and Drug Administration (FDA) requesting that FDA extend the deadline for comments on the document, *FDA Concept Paper: Drug Products that Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness* (the Concept Paper), to a date 90 days after all materials are placed in the public docket.

In your letter, you state that that the bibliography to the Concept Paper had not been entered into the docket as of July 21, 2000. However, each of the items in the bibliography was, indeed, placed in the public docket before that date. In accordance with FDA procedure, documents that do not contain copyrighted material were made available on the Internet (at <http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3634b1x.htm>) and all documents, including those with copyrighted material, were made available for viewing at the Dockets Management Branch. Jayne Peterson, of our Advisors and Consultants Staff, discussed this policy and the availability of the documents in a telephone conversation with your legal counsel, Jeffrey Gibbs of Hyman, Phelps & McNamara, P.C., on July 3, 2000. The Agency encourages you or a member of your organization to examine the documents at the Dockets Management Branch. The office, located at 5630 Fishers Lane, room 1061, Rockville, MD, is open Monday through Friday, 9:00 am to 4:00 pm. Because the copyrighted materials listed in the bibliography are articles from established medical journals and chapters of textbooks, reference manuals, and the *United States Pharmacopeia*, they should also be available at a local public library or medical library.

Notwithstanding the fact that the materials were made available several weeks ago, FDA is extending the deadline for accepting comments on the Concept Paper to October 13, 2000. The Agency believes that with this extension, the International Academy of Compounding Pharmacists should have ample time to evaluate and comment on the Concept Paper.

Sincerely,


Jane A. Axelrad
Associate Director for Policy,
Center for Drug Evaluation and Research

cc: Docket 00N-1357