



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

July 15, 2002

Jonathan W. Emord, Esq.
Emord and Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

Dear ~~Mr. Emord~~ ^{Jonathan}:

This is a follow-up to our conversation last Friday. I very much appreciate your willingness to extend the 100-day deadline for your client Dr. Kyl Smith's health claim petition for phosphatidylserine for a month. I would like to have you in at your earliest convenience to address the new dietary ingredient issue we discussed.

I have a slight emendation I would like to make to our discussion. Because we will need time to review any new information you may decide to submit, I propose to treat your one-month research and decisionmaking period as stopping the clock on our review of the petition. As of our conversation on Friday, there were 16 days left in the agency's review period, which was due to end on July 28. Accordingly, I propose a new deadline of September 13 (16 days after August 28).

If this is acceptable to you, I would be grateful if you would reply in writing to confirm your agreement with the proposed new deadline. As you know, if FDA and the petitioner do not agree on an extension before the deadline, the petition would be deemed denied under 21 C.F.R. 101.70(j)(2).

Please do not hesitate to call me about this if you wish to discuss.

Sincerely,

Daniel E. Troy
Chief Counsel
Food and Drug Administration

cc: Christine L. Taylor, Ph.D.

02P.0413

LETA