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March 6, 2007

Division of Documents Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2006D-0480

To Whom It May Concern:

I am writing this comment in response to a call from the Food and Drug Administration (FDA) for "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration: Availability".

I am writing this comment from the perspective of a traditionally trained, fully licensed and board certified nephrologist (kidney specialist) who practices medicine and performs clinical research at an academic medical center in the United States (Mayo Clinic) and is under the usual supervision of our Institutional Review Board (IRB).

My comment is prompted by a current research project using a biologically based treatment from Complementary and Alternative Medicine (Ayurveda) that is on indefinite hold. The research project was approved by our IRB before this call for Guidance was announced. It was determined through informal conversations between one of our attorneys and an FDA official that no Investigational New Drug (IND) number was required because this CAM product was basically marketed as a food supplement. On this basis, we formulated a budget and enrolled about 75% of our anticipated patients. Currently we are unable to enroll the last patients because of the FDA determination around the time of this call for Guidance that the product needed an IND. Our study coordinator expects to be paid, yet we have no funds to cover this indefinite extension of the project while our IND application is being considered.

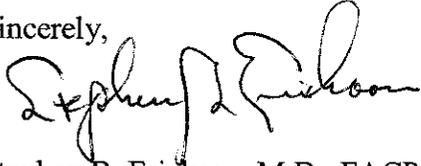
My concern is not whether this research product requires an IND according to current guidelines. It does. My concern is that because this product is sold as a food supplement, there is a **double standard**. Any person living in the United States can buy this product over the counter without any supervision what-so-ever. All they need is the money to pay for it. Yet a research study to determine whether this product is safe and effective for one of its uses under the careful supervision of a highly trained medical specialist (me) and the oversight of an IRB has been halted and perhaps ruined by the need for IND information, some of which does not exist.

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If you ask me, I think all biologically based "supplements" should meet medication standards including an IND study *before* they are marketed. No one asked me. It was the will of the American public reflected by Congress that supplements be minimally regulated. Therefore I think we should have a **single standard**. If in the wisdom of our government, a product may be sold over the counter without supervision, it need not qualify for an IND retrospectively when one tries to assess its safety and effectiveness.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen B. Erickson". The signature is fluid and cursive, with the first name being the most prominent.

Stephen B. Erickson, M.D., FACP

P.S. These comments do not necessarily reflect the opinions of Mayo Clinic.