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VIA ELECTRONIC SUBMISSION

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

Re: Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards on Investigational New Drug Applications--Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; Reopening of the Comment Period; Docket No. FDA-2010-D-0503

CHPA is the 133-year-old trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements (chpa.org). In response to the 2013 Investigational New Drug (IND) Guidance "Investigational New Drug Applications (INDs)—Determining whether Human Research Studies can be Conducted without an IND," CHPA submits the following comments and appreciates the opportunity to provide information on the potential adverse effects this may have on our members.

The 2013 IND Guidance, particularly Section VI, Parts C and D, significantly expands the scope from FDA's 2010 draft Guidance on the topic. Under the new IND Guidance, most studies of foods – other than those designed solely to assess safety and tolerance – would need to be studied as Investigational New Drugs. This interpretation fundamentally changes FDA's approach to regulating food and food research, disregards longstanding legal distinctions between foods and drugs, and overrides clear congressional intent to differentiate foods bearing certain claims (structure/function claims, health claims, and medical food claims) as distinct from drugs. Further, it is reasonable to question the need for, and the cost-benefit assessment of, trying to fit basic nutrition research into the Investigational New Drug model and subject such studies to both CDER and CFSAN oversight.

As long as the endpoints of clinical studies on foods are consistent with these statutory-based exemptions from drug status, it is simply wrong for FDA to summarily declare that investigational new drug requirements govern such investigations. Such a broad interpretation of the Agency's statutory authority serves only to arbitrarily inhibit valuable nutrition-based

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa.org • OTCsafety.org

research at precisely the time such research is desperately needed. Already, the IND Guidance has had a paralyzing effect on clinical nutrition research in the U.S., and has created confusion and uncertainty with respect to the status of ongoing and planned studies. Policies imposed by the IND Guidance will burden and likely confuse researchers, sponsors, and institutional review boards, have the real potential to negatively impact overall dietary guidance, and will stifle innovation by adding new regulatory barriers and costs for product development. If FDA is concerned with claims being made for certain food products, the Agency already has appropriate enforcement authority to address violative claims without impeding clinical research.

Thank you for your attention to this important issue. Please feel free to contact me should you require further information.

Respectfully submitted,

Jay Sirois, Ph.D.
Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association