American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

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Dockets Management Branch (HFA-305)
Food and Drug Administration
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Re: Docket No. 96N-0417

To whom it may concern:

On behalf of the 57,000 members of the American Academy of Pediatrics (AAP), I offer the following comments regarding the Proposed Rule, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements* (21 CFR Parts 111 and 112).

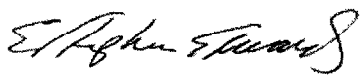
The AAP is the national professional organization representing physicians who provide health care to our infants, children, and adolescents. In that role, the AAP has developed extensive policy guidelines regarding adequate and safe diets for these age groups. Among other issues, members of the AAP have been concerned by the frequent reports of adverse events associated with the use of dietary supplements among all age groups including children (1,2). These concerns have been heightened by the widespread use of dietary supplements in the population as a whole and among our young patients (3,4).

The Dietary Supplement and Health Education Act (DSHEA) of 1994 defined dietary supplements to include a broad range of herbs and drugs of plant origin. While, many of these substances are pharmacologically active, DSHEA does not provide the level of consumer protection applied to conventional medicines. A list of our concerns with DSHEA is given in the *Handbook of Pediatric Environmental Health*, published by the AAP. These include:

- Lack of pre-market testing;
- Lack of licensing process;
- No requirement for safe packaging, such as child proof containers;
- No proof of nutritional claims required, either on the label or in marketing;
- Pharmacologically active substances can be marketed as dietary substances as long as no therapeutic claims are made; and
- No provision for mandatory reporting of adverse events.

As published, the proposed rule requiring current good manufacturing practices for dietary ingredients and dietary supplements would assure identity, consistency, purity, quality and strength. It also would require appropriate packaging and labeling. The proposed rule, therefore, is a laudable first step toward correcting what the Academy views as a deficiency of the Dietary Supplement and Health Education Act (DSHEA). In light of the pharmacological nature of most dietary supplements and the impact they can have on the metabolism, the AAP strongly urges the FDA to take further action by regulating dietary supplements similar to the requirements for drugs and biological products.

Sincerely,



E. Stephen Edwards, MD, FAAP
President

ESE:pk

References:

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2. Zuckerman M, Steenkamp V, Stewart MJ. Hepatic veno-occlusive disease as a result of traditional remedy: confirmation of toxic pyrrolizidine alkaloids as the cause using an in vitro technique. *J Clin Pathol*. 2002;55:676-679.
3. Speigelblatt L, Laine-Ammara G, Pless IB, Guyver A. The use of alternative medicine by children. *Pediatrics*. 1994;94:811-814.
4. Ottolini MC, Hambrueger EK, Loprieato JO, et.al. Complementary and alternative medicine use among children in the Washington DC area. *Amb Pediatr. 2001;2:122-125.*