LAW OFFICES OF
CHRISTOPHER E. GRELL

THE MONADNOCK BUILDING
685 MARKET STREET
SUITE 540
SAN FRANCISCO, CALIFORNIA 94105
(415) 541-9866
FAX (415) 541-9869

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May 2, 1997

Dockets Management Branch
HFA-305
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, Maryland 20857

Re: Dietary Supplement CGMP Consumer Comment

Dear Sir:

As recognized in the attached statement of Michael Taylor, one-time Deputy Commissioner For Policy U.S. Food and Drug Administration (Exhibit 1), the primary goal of the FDA is first, the safety of the products sold over the counter (p.7). However, there are no laws in effect to assure the public that dietary supplements are safe since there is no requirement that safety tests be submitted to any government agency, before dietary supplements are marketed.

Without such a requirement, how can the FDA represent or imply by their silence, that these products are safe. Indeed, as noted by a former FDA agent who now represents several Dietary Supplements, one suggested method to testing ingredients used in Dietary Supplements is to market them and see if the FDA does anything. (See Exhibit 2.)

Consequently, GMP should be established to accomplish the principal goal of the FDA, assurance to consumers that these products are safe. Anything less violates the primary goal of them FDA.

The second primary goal, as expressed by Mr. Michael Taylor is to see to it that these products are properly labeled. Again, based on my personal experience, it is clear that this goal is not being achieved. For example, as reflected in the enclosed letter of Ms. Diane Thompson, the FDA concluded the dietary supplements containing stimulant laxatives should contain warnings to the consumer. Yet, as her letter also reflects, no such action has ever been taken by the FDA. Why not? If proper labeling is a primary goal, how can the FDA represent to the public that it is doing its job when by its own admissions these

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"Products" are not labeled properly and the FDA is not doing a thing about it. (See Exhibit 3.)

It would also become apparent from a trip to your local health food store, drug store and/or grocery store, that many dietary supplements contain ingredients that are not approved food additives or GRAS foods. The FDA is well aware of this and still chooses to do nothing. Why?

It has also come to my attention that several dietary supplement manufacturers selling ephedrine containing products are "spiking" their products with synthetic ephedrine HCL. I am also told that the FDA is aware of this practice and has chose to do nothing. Again, if proper labeling is a primary goal, shouldn't the consumer know that these "so-called" all natural dietary supplements are being spiked with synthetic ingredients.

Next, I am at a loss as to why Dr. Yetley opposed efforts to adopt the German Commission E Monographs as a basis for GMP's. (Exhibit 4.) Again, I am enclosing a letter to the editor that I wrote which was published in the magazine "Herb' For Health." (See Exhibit 5.)

In case you are not aware of the report, I am enclosing an article from the Vitamin Retailer describing the growth of this industry. (See Exhibit 6.)

I am also enclosing a copy of a previous letter I sent expressing my concerns over letting the Dietary Supplement industry develop GMP's. (Exhibit 7.)

In short, I urge the FDA and the Dietary Supplement Commission to empanel a group of unbiased experts to review all proposals submitted by industry and to submit their own proposals to achieve the objectives that the FDA is supposed to follow, i.e., safety and proper labeling. As it now stands, the labeling of many of these products is a sham that unfortunately is jeopardizing the health and safety of millions of Americans.

Thank you.

Very truly yours,

Christopher E. Grell

CEG:lf

Enclosures

diettea.res\dockmana.let