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The Honorable Don Young
House of Representatives
Washington, D.C. 20515

Dear Mr. Young:

This is in response to your letter of April 29, 1997, on behalf of William Burton Pettis of Seattle, Washington, regarding the proposed rule on current manufacturing practice in manufacturing, packing, or holding dietary supplements (docket #: 96N-0417).

We appreciate Mr. Pettis' interest in the Food and Drug Administration's (FDA) regulatory process and have forwarded his letter to the Dockets Management Branch.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: HFW-2
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HFW-12
HFA-305
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96N-0417

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DON YOUNG
CONGRESSMAN FOR ALL ALASKA
WASHINGTON OFFICE
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TELEPHONE 202/225-5765
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COMMITTEE ON
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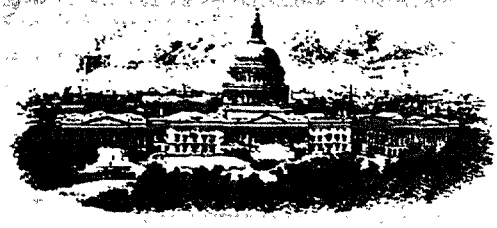

Congress of the United States
House of Representatives
Washington, D.C. 20515

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April 29, 1997

Food and Drug Administration
Ms. Diane Thompson
Assoc. Commissioner for Legislative Affairs
Room 1555
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Thompson:

I have enclosed the communication which I received from my constituent Mr. William Burton Pettis (2410 NW 57th #4, Seattle, WA, 98107), regarding a matter under your department's jurisdiction. His particular concerns are described in his letter.

I would appreciate your reviewing Mr. Petti's letter regarding dietary supplements and providing me with any comments. Please forward your reply to my Washington, D.C. office.

Thank you for your continued time and courtesy in being attentive to the concerns of my constituent.

Sincerely,

DON YOUNG
Congressman for all Alaska

6-9-97 Rt. call 6/11
Left voice message will
try to call me on for
copy of constituent letter
to OLA - middle section
for. sent for 6/11

OLA Rec'd 6/9/97

No. 97-4597

DATED MATERIAL

William Burton Pettis
2410 NW 57th #4
Seattle, WA 98107
206-784-6872
E-mail bh787@scn.org

April 21, 1997

Office of Representative Don Young
United States House of Representatives
Washington, DC 20510

Dear Honorable Representative Young,

I am a constituent of yours who is presently studying natural medicine at Bastyr University in Seattle, Washington. I am writing you in regards to the Current Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements; Proposed Rule, [Docket No. 96N-0417] RIN 0910-AA59 that has been presented by the Food and Drug Administration for review. I have enclosed a copy of my letter of comment on this proposed regulation for your review. I encourage you to review the FDA document as well.

I look forward to practicing medicine in our home state. This regulation if implemented would have a disastrous effect on my ability to make a living and would be an insult to the profession I have chosen. There is no need for the FDA to impose such heavy regulation on qualified healthcare providers.

If the manufacturing industry regulations were placed upon practitioners of natural medicine, the consumer would loose access to a quality and inexpensive form of medical care. They would be forced to purchase products that would not be designed specifically for their needs. Their quality of care would be dramatically diminished, as the central core of their medical practitioner's practice would be abolished by the proposed FDA regulations.

I believe we should protect the citizens of our state from having their quality of healthcare lowered by needless federal regulation. This regulation would create an economic environment that would destroy my medical practice. I request that you voice my concerns as well as your own to the FDA. The comment deadline is May 7, 1997.

I respect your ability to adequately serve our state and country. I thank you for your time in review of this important healthcare issue. I look forward to your future correspondence.

Sincerely,

William B. Pettis

Comment on [docket No. 96n-0417] RIN 0910-AA59.

From; William B. Pettis
2410 NW 57th #4
Seattle, WA 98107
E-mail: bh787@scn.org

April 21, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23,
Rockville, MD 20857

To Whom It May Concern:

This letter should serve as my official comment regarding FDA Docket No 96n-0417, RIN 0910-AA59, Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Supplements. I am currently studying natural medicine at Bastyr University in Seattle, Washington.

In review of the document listed above, I was pleased to see that the "natural products industry" is attempting to reach a level of production proficiency and safety that is currently being practiced by Practitioners of Oriental Medicine as well as other healthcare professional across the United States. Dietary supplements that have been routinely prepared for consumers by "qualified" healthcare practitioners have been prepared safely in our country for many years. Chinese herbal medicine, which is used by thousands of Americans daily, has a history of safe and effective use for over two thousand years. Natural products were used to supplement the American diet long before pharmaceutical drugs replaced them. The use and preparation of natural dietary supplements is an innate part of Native American and Asian American cultures and is rapidly becoming an important part in the general populations life.

The Industry Draft has benefits for the manufacturing industry, but this draft will create unfavorable conditions for the consumer, and for qualified healthcare practitioners. The measures contained in this draft would require qualified healthcare practitioners to implement production controls and standards that are not economically practicable. Furthermore, qualified healthcare practitioners are already producing the end-results that the industry and the FDA are attempting to achieve by implementing this draft. This draft places an unnecessary burden on qualified healthcare practitioners in addition to placing the consumer and small natural products manufactures at an economic disadvantage.

Thousands of Americans will be forced to buy commercial products if this proposed regulation is applied to all parties who manufacture natural dietary supplements. Practitioners would no longer be able to meet their patient's needs due to such heavy regulation. You should note that many Americans choose to use natural medicine as their means of primary healthcare and should not have their quality of professional care decreased by placing needless regulations upon their qualified healthcare practitioner(s).

Secondly, the negative effects that this regulation would have on the health of Americans who choose to use natural medicine would be profound! Chinese herbal medicine depends on the ability of the practitioner to be able to mix herbal/natural product preparations that are specific to the needs of the individual. The ingredients of these preparations are adjusted as required by the healthcare practitioner. Although, the industry has been able to develop some of the basic formulas used in Chinese medicine they have not adequately produced the variety of formulations that are usually required by most consumers who choose this efficient method of promoting wellness. The ability to choose and create formulations as needed by trained healthcare professionals allows for an infinite number of treatment options.

The production of Chinese herbal preparations requires a thorough knowledge of the animal, plant and other natural substances used. The large number of qualified healthcare practitioners who currently manufacture natural dietary supplements without incident and with positive outcomes for their consumers adequately represents this knowledge. The ability to manufacture and design tinctures, powders, extracts, capsules as well as other safe means for administration of natural products is the foundation of most forms of natural health care and should not be destroyed by placing unnecessary regulations on competent healthcare providers. These regulations will destroy the individual professional practices that have been established by hard-working qualified medical professionals.

I urge you to review my comments and to explore better means of insuring good manufacturing practice in manufacturing, packing, or holding dietary supplements. Ideally, a plan that does not destroy competent forms of healthcare delivery or that places devastating financial burdens on consumers and medical providers.

Sincerely,

William B. Pettis