DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Barbara Boxer
United States Senator
1700 Montgomery Street, Suite 240
San Francisco, California 94111

Dear Senator Boxer,

Thank you for your letter of January 27, 2000, on behalf of your constituent, Mr. Alex Kononchuk, President of K & K Laboratories, Carlsbad, California, regarding his opposition to the proposed rules for good manufacturing practices (GMP) for dietary supplements. The Food and Drug Administration (FDA or the Agency) appreciates the importance of the issues raised by your constituent.

FDA held two public meetings on September 28 and October 21, 1999, to solicit comments to assist FDA's Center for Food Safety and Applied Nutrition (CFSAN) to understand the economic impact that any proposal to establish current GMP's regulations for dietary supplements may have on small businesses in the dietary supplement industry. These meetings were intended to give interested persons, including small businesses, an opportunity to comment on the economic impact that such a proposal may have on small businesses and for an open discussion of the manufacturing practices of small businesses in the dietary supplement industry. In addition, these public meetings were intended to fulfill part of the outreach requirement of the Small Business Regulatory Enforcement Fairness Act of 1996. The agenda included topics regarding the small business entities' manufacturing practices and standard operating procedures for: (1) personnel; (2) buildings and facilities; (3) equipment; (4) laboratory operations; (5) production and process controls; and (6) warehousing, distribution and post-distribution of raw, intermediate and final products. The meeting included a discussion about the verification of the identity, purity, and composition of dietary supplements and dietary supplement ingredients.

96N-0417

C98 /ANS

The public comment period for this issue was open until November 21, 1999. We have submitted your constituent's letter with your cover letter to the docket (96N-0147) established for this issue. FDA plans to publish a proposed rule on GMPs this year. Once the proposed rule is published, dietary supplement manufacturers will have an opportunity to voice their opinions and concerns regarding how FDA should implement GMPs for the industry.

We trust this information responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to contact us.

Sincerely,

/s/ Michael Ecke

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(Docket No. 96N-0147)

BARBARA BOXER
CALIFORNIA

COMMITTEES:
BUDGET
ENVIRONMENT AND PUBLIC WORKS
FOREIGN RELATIONS

United States Senate

HART SENATE OFFICE BUILDING
SUITE 112
WASHINGTON, DC 20510-0505
(202) 224-3553
senator@boxer.senate.gov
http://boxer.senate.gov

January 27, 2000

Ms. Diane Thompson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
HFW-1, Room 15-55
Rockville, Maryland 20857

Dear Ms. Thompson:

Enclosed please find a copy of the correspondence Senator Boxer received from Alex Kononchuk, regarding proposed rules for the nutritional supplement industry.

Senator Boxer is forwarding the attached for your review and consideration. Any information you can provide in response to the concerns expressed by Mr. Kononchuk will be most appreciated.

Thank you for your assistance in this matter. Please respond to Senator Boxer's San Francisco office, Attention: Irene Nikkah.

Sincerely,

Paula L. Maul for

Eric J. Vizcaino
Director of Constituent Services

EJV/isn
Enclosure
cc: Alex Kononchuk

No. 00-748

☐ 1700 MONTGOMERY STREET
SUITE 240
SAN FRANCISCO, CA 94111
(415) 403-0100

☐ 312 N. SPRING STREET
SUITE 1748
LOS ANGELES, CA 90012
(213) 894-5000

☐ 501 "I" STREET
SUITE 7-600
SACRAMENTO, CA 95814
(916) 448-2787

☐ 1130 "O" STREET
SUITE 2450
FRESNO, CA 93721
(559) 497-5109

☐ 600 "B" STREET
SUITE 2240
SAN DIEGO, CA 92101
(619) 239-3884

☐ 201 NORTH "E" STREET
SUITE 210
SAN BERNARDINO, CA 92401
(909) 888-8525

"Quality You Can Trust"

K&K LABORATORIES, INC.

November 22, 1999

The Honorable Barbara Boxer
United States Senate
600 B street, Suite 2240
San Diego, CA 92101

Dear Senator Boxer,

Please review the enclosed correspondence that we sent to the FDA regarding proposed rules for the nutritional supplement industry. We believe that the end result of accepting these procedures would be to drive small manufacturers, such as ourselves, out of business and greatly reduce the benefits that competition brings to consumers. The proposals are mainly being pushed by very large manufacturers seeking to use the regulatory process to eliminate smaller competitors that would otherwise survive in the current regulatory situation.

We respectfully request that your office investigate this situation and we hope that Congress will act to protect small businesses such as ours from needless and very costly new regulations.

Thank you for your attention.

Sincerely,

Alex Kononchuk
President

Encl.

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I urge the FDA to reject the new manufacturing practices and use its existing authority as the need arises.

Sincerely,

Alex Kononchuk
President

"Quality You Can Trust"

K&K LABORATORIES, INC.

November 17, 1999

Dockets Management Branch (HFA-305)
Docket No. 96N-0417
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear FDA Administrator,

I oppose the suggested regulation changes relative to the nutritional supplement industry outlined in the FDA'S comment request letter of September 9, 1999. Imposing additional one-size-fits-all standards upon the manufacturing of vitamins and related products is both unnecessary and ultimately contrary to the best interests of the buying public.

The proposals are unnecessary because they address a non-existent problem. Everyday, some American dies as a result of taking drugs that have been approved as safe by the FDA. This is not remotely the case with vitamins. The FDA already has the authority to inspect nutritional supplement plants, respond to complaints, and embargo batches, if necessary. If the FDA chooses to allocate its resources to other industries within its jurisdiction, it is because the problems with this industry are minor in comparison. I believe that the rules are proposed solely to allow the FDA to intrude into the nutritional industry to a degree that Congress has opposed since the Proxmire Amendment.

The proposals will also harm consumers because they are anti-competitive. Large manufacturers, including pharmaceutical companies who abandoned the vitamin markets as not profit worthy in the past and now are buying up drugstore chains, may have no difficulty in adapting to these changes. They can write a few checks and hire people and equipment they don't really need. Small manufacturers, such as ourselves, could be driven out of business by large expenditures imposed upon us but not justified, considering the high quality products we produce and sell. Spokesmen for one marketer dominated trade association, the NNFA, which is proposing similar rules for its manufacturing members, acknowledge that some smaller firms could be forced out of business by the costs of attempting to comply. In many smaller operations one or two individuals wear all the hats, yet produce products of the highest quality. We in turn supply companies too small for the big boys to bother with. Competition in price and product availability is in the best interest of the consumer. If at the end of the day all we are left with are General Nutrition Stores and One-A-Day and the supermarkets, the public loses out. If size was a virtue, and lack of competition a non-issue, why is the government pursuing Bill Gates?

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