

K & K LABORATORIES, INC.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Alex Kononchuk".

Alex Kononchuk
President