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United States Senate

WASHINGTON, DC 20510–2003

July 1, 2003

Mr. Amit Sachdev
Associate Commissioner for Legislation
Food and Drug Administration
5600 Fishers Lane, Parklawn Building
Room 15-47
Rockville, Maryland 20857

Dear Mr. Sachdev:

I am writing to request your consideration of the attached correspondence from Ms. Mary Massey and Mr. Jack Meiners. Please respond directly to Ms. Massey and Mr. Meiners and send a copy to Amy Costello of my staff. If you have any questions, please call Ms. Costello at (202) 224-4654.

Thank you for your assistance.

Sincerely,

Barbara A. Mikulski
United States Senator

BAM:ac
Enclosure

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03-3305

2012 Forest Dale Drive
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June 4, 2003

The Honorable Barbara A. Mikulski
709 Senate Hart Office Building
Constitution Avenue and Second Street NE
Washington, DC 20510

Dear Senator Mikulski:

The 1994 Dietary Supplement Health and Education Act states that "...other than the manufacturer's responsibility to ensure safety, there are no rules that limit serving size or the amount of a nutrient in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval."

We would very much like to know:

1. Why does the use of supplements and herbal remedies that can **lead to illness and death** continue to be unregulated. According to *Washington Senior Beacon*, "FDA proposes dietary supplement standards," June 2003, "Ephedra—an herbal stimulant blamed for dozens of heart attacks, strokes and deaths—is the most notorious...." of unregulated dietary supplements. A recent example is the baseball player who was using a derivative of Ephedra: his death was linked to this usage. In the absence of government regulation, no one checks on the **content** of these alternative medicines and nutritional supplements. For example, does the glucosamine/chondroiton that one of us takes for arthritis have the amount of active ingredient shown on the label? Also, **interactions** of dietary supplements and herbal remedies with each other and with conventional, controlled pharmaceuticals are not subject to regulation. It is past time for FDA to protect us all from potentially harmful dietary supplements and herbal remedies, to assure that they are not potentially hazardous, that they are safe to take in combination with other supplements and with controlled pharmaceuticals, that their contents are as labeled, and that they are free from contaminants (bacteria, lead, for example). **When can we count on this kind of control by FDA?**

2. Why is it that multivitamins contain **100% or more** RDA (recommended daily allowance) of some vitamins and minerals (Centrum Silver, for example, contains 150% of Vitamins E and B6 and 417% of Vitamin B12)? Many Americans who can afford dietary supplements usually get plenty of vitamins and minerals in fairly well balanced diets but may still want supplements. Only a malnourished person might need as much as 100% RDA in a multivitamin tablet, but is not likely to be able to afford

supplements. It seems that 100% or more of RDA in any dietary supplement is **overkill**, possibly **harmful.** Why not just 50% RDA for any of the contents of a multivitamin? **Will you please support legislation to require FDA review and approval of dietary supplements?**

3. A *Washington Post* article, "Picking a Bone With Vitamin A," February 4, 2003, warns of possible bone damage when too much Vitamin A is ingested. The National Academy of Sciences' Institute of Medicine has determined that the recommended daily allowance (RDA) for Vitamin A is 2300 IU for women and 2970 for men. The Vitamin A in Centrum Silver was recently reduced from 5000 to 3500 IU, still more than 100% RDA for women and men. Spectrative Senior (a CVS Pharmacy product) contains 5000 IU of Vitamin A, more than twice the recommended amount for women! **When can we expect a change in the current approved RDA for Vitamin A and other vitamins that exceed the RDA in dietary supplements?**

We believe it is important to the health of American citizens for the FDA to regulate the contents and safety of all dietary supplements.

We look forward to hearing that you have made such a recommendation to the appropriate Senate committee and that you support such legislation.

Sincerely,

Mary C. Massey

Mary C. Massey

Jack P. Meiners

Jack P. Meiners