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All consumers of dietary supplements, including people with HIV/AIDS have a right to expect that the products we use are pure and safe and that they contain the substances claimed on the label in the amounts specified. Guaranteeing the safety of supplements and the accuracy of labels with regard to contents is the responsibility of both the manufacturers and the Food and Drug Administration (FDA).

Consumers also have a right to accurate, clear and non-misleading information about dietary supplements. Currently, however, there are only a handful of informative claims with which the FDA agrees. Totally unsubstantiated health-related claims are essentially undifferentiated with those that are backed by specific, well-designed clinical studies. The practice of following virtually all manufacturer-driven label claims with FDA's statement that "these claims have not been evaluated by the FDA" does not provide enough information for most consumers. FDA's disclaimer may, in fact, mislead people to believe that all claims not evaluated by the FDA are more or less equivalent.

With all of the above factors in mind, we would like to address five interrelated areas of concern regarding the regulation of dietary supplements:

Labeling Information
As indicated below, dietary supplements should contain sections or "boxes" that provide the following information: "supplement facts" (active ingredients, etc.), health claims and FDA's disclaimers (see "Health Claims"), a safety profile (see "Safety and Purity") and GMP (Good Manufacturing Practices, see "Safety and Purity").

Safety Profile
The system for reporting adverse events associated with dietary supplements should be enhanced and made "consumer friendly". Outreach and education to those who use supplements must become a high priority.

Product safety should be evaluated using standardized and objective criteria to determine if adverse effects are likely to occur or if they have occurred. If adverse events have been identified, then it should be further determined if they rise beyond an objective threshold past which FDA action is required. Once verified, the current mechanisms for FDA response are adequate.

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Dietary supplement labels should indicate if a product may be associated with historically known or reported adverse effects and contraindications. This information would be contained in the "Safety Profile" section of the label (see "Labeling Information"). Labels for formulas containing

new biochemical ingredients would also indicate that the product was associated with a very limited history of use.

All dietary supplement labels should be required to devote a small but prominent section to inform consumers if a product is manufactured under a credible standard of GMP. This standard - as proposed by various manufacturers associations--should be higher than the standard for food but not as onerous as that which is required for pharmaceutical drugs. The FDA would supervise verification of a manufacturer's compliance with GMP for selected products. The Agency would also periodically check for contaminants in a variety of dietary supplements to assure their purity.

Health Claims

If a manufacturer or distributor of a dietary supplement makes a health or disease-related claim, that claim must be evaluated under an objective standard to determine the degree to which the claim is valid.

Once evaluated, claims would be rated on a scale of 1 to 4. The lowest rating (level 1) would be associated with the absence or extreme paucity of scientific evidence while the highest rating (level 4) would indicate that there is "significant scientific agreement" and that FDA agrees with the claim. Levels 2 and 3 claims would require varying degrees of scientific proof and/or verification of long-term history of use and would be accompanied by an FDA disclaimer. Appropriately, level 2 would require a higher standard of proof than level 1, while level 3 would represent a considerable body of scientific studies and other specific evidence that clearly placed it above level 2.

Consumer Outreach and Education

The goal in implementing the proposed label additions and changes is to benefit consumers and assist us in making informed choices. This requires extensive consumer outreach, media campaigns as well as educational seminars and public meetings.

A collaborative effort that includes input from a broad range of consumer groups, scientists, FDA officials and representatives from the dietary supplement industry must be mounted in order for labeling information to become genuinely useful for those who use supplements. Assisted by others in the collaboration, consumers should take the lead in determining how best to approach the goal of comprehensive, "user-friendly" labels and to avoid consumer deception and fraud.

Funding and Resource Allocation

To allow FDA to properly enforce current laws regarding dietary supplement safety, content and potency claims and health fraud, funding for staff enhancement and training must be increased. More money must also be set aside for revising and improving labels that will be used by consumers to make important health care decisions and to educate consumers about the new label changes.

We propose that Congress authorize the allocation of some additional funds to assure that the FDA can monitor the safety and content of dietary supplements.

We further propose that funding for necessary improvements in labeling and evaluation of label claims as well as a portion of the consumer outreach efforts be substantially obtained through a nominal surcharge on each unit of dietary supplements sold in the U.S.

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