STATEMENT

OF

SHIRLEY STARK

ASSISTANT ATTORNEY GENERAL OF NEW YORK

before the

HOUSE COMMITTEE ON GOVERNMENT OPEERATIONS

SUBCOMMITTEE ON HUMAN RESOURCES AND

INTERGOVERNMENTAL RELATIONS

ON

DIETARY SUPPLEMENTS

Good morning. I would like to begin by thanking Chairman Towns and the members of the Government Operations Sub-Committee for this opportunity to discuss the issue of regulation of dietary supplements. As you may know, the New York State Attorney General, along with other state attorneys general, has been actively involved in the areas of food, drug and dietary supplement advertising and labeling over the past few years. In addition to filing comments with the FDA, we have taken enforcement action and we have entered into many settlement agreements with manufacturers and purveyors of these products regarding labeling and advertisement issues.

As you are well aware, there is a vigorous debate going on in Congress, in the media, at the FDA and among the public at large about how dietary supplements should be regulated. Barely a week goes by without a report in one of the national newspapers documenting the dangers of some herbal product, "body building" amino acid or even some multi-vitamins. On one side of the debate, the industry accuses FDA of trying to over-regulate dietary supplements and treat them as they would prescription drugs, thereby denying consumers ready access to supplements. On the other side of the debate are consumer protection agencies who believe that supplements are not subject to nearly enough regulation and cite examples of people dying or suffering severe injuries from the use of some dietary supplements. The debate has thus far left the public in a fog and Congress and FDA grappling with the difficult issues of how to regulate these products.

While dietary supplements include seemingly safe products like essential minerals and vitamins which have recognized nutritional benefits, the term also encompasses many products which are of questionable safety, such as some herb products and high potency amino acid supplements. Many of these products have no recognized role in nutrition and make what appear to be therapeutic drug-like claims on their labels and in advertisements. Although the harm that can result from use of these products is as serious as that which can result from improper use of any prescription drug product, these supplements usually do not receive the same review as drugs. That fact became only too clear with the outbreak of illnesses in the summer and fall of 1989 during which 38 deaths resulted from the use of dietary supplements containing L-Tryptophan, an amino acid.

Supplements which are marketed to be used as cures or treatments for disease are considered drugs and must be generally recognized by scientists as safe and effective for their intended use, or must have FDA approval prior to marketing. This requirement, however, is most often honored in the breach. Consumers have suffered serious injury and death from unsafe and ineffective dietary supplements, which were neither generally recognized as safe and effective nor had received prior FDA approval, and yet were marketed to the public as cures for various diseases and ailments or as "magic pills" for weight loss. Other consumers have suffered serious injury and death as a result of delaying or foregoing proven treatments while they relied on false claims and promises of cures and pursued ineffective unconventional treatments with nutritional supplements. The dangers which can result from use of supplements effectively marketed as cure-alls are no less serious than those which can result from ingestion of a drug.

The use of some herbal supplements presents a particularly dangerous situation. FDA has stated that many of the herbs currently marketed have no history of food use or use in concentrated forms, and are clearly hazardous. While marketers of these products sing their praises, they fail to reveal the potential dangers, thus fraudulently

inducing people to consume these products. The herbal product, San-Kee, for example, was falsely marketed throughout the country as a Chinese herbal remedy for arthritis and has been shown to contain prescription drugs as well as unsafe levels of lead and cadmium. Most herbal products do not carry warnings on their labels and are not required to do so.

An article by Marian Burros that appeared in The New York Times recently focused on the dangers of herbal products such as comfrey, which can cause permanent liver damage, and chaparral, which can cause toxic hepatitis. Another New York Times Burros article detailed the frightening adverse reactions that can result from consuming ephedra, a widely available herb marketed for everything from decongestion to weight loss. In the case referred to by Marian Burros, a Washington bank branch manager had not slept more than one hour a night for ten nights and began engaging in such irrational behavior after taking ephedra for six weeks to lose weight that he was locked out of his office. As the bank manager, stricken with ephedrine poisoning, later commented when he returned to normal, because ephedra was "natural" he was "seduced into the idea that it's safe." Because no warnings are present on labels, consumers have no way of knowing the potential dangers of such products, or even that their reactions may be attributable to the herbs they ingested.

A particularly glaring example of unsubstantiated therapeutic claims made for herbal supplements occurred a few years ago when the USHA Herbal Research Institute, run by a self-styled nutritionist calling himself "Dr. Sebi", advertised in the Village Voice and the Amsterdam News that "AIDs HAS BEEN CURED" by USHA and that they also specialize in cures for Leukemia, sickle cell anemia, herpes, lupus and other diseases. For an initial fee of $500 and $80 for each additional visit, patients were told they could be cured of AIDS and other diseases. The "cures" consisted of various herbal products, for each of which USHA made therapeutic claims. Eva Therapeutic Salve, for example, was referred to in USHA's brochure as follows:

> Eva Therapeutic Salve - "Eva is very effective on major skin problems, in prenatal use, against poor circulation, cancer, cysts, hemorrhoids and arthritis."

In fact, these claims were false. Our office filed suit against USHA and entered a consent agreement under which USHA can no longer make therapeutic claims for any of its products.

Dietary supplements containing amino acids are another insidious example of supplements whose safety is suspect, yet which are still regulated as foods, despite the fact that they are touted as cures for all kinds of ailments. FDA's Task Force Report on dietary supplements recommends that amino acids containing dietary supplements be treated as drugs because the primary intended use for these products is therapeutic and not nutritional. In this way, safety issues could be resolved by requiring that manufacturers prove product's safety before it could be sold. We believe that the implementation of such a policy by FDA would best protect public health and would help to prevent the onset of epidemics attributable to the use of supplements such as that which we witnessed with the amino acid L-Tryptophan.

Even supplements which provide an acknowledged health benefit to certain segments of the population may contain hidden dangers which should be disclosed to the public. Public trust is high that products designed to be consumed by the public are safe, and are assumed to be "tested" by someone. Commonplace and seemingly innocuous vitamin and mineral supplements sometimes lack informative warning statements regarding the fact that they can be harmful in excessive amounts. Our office recently became aware of the problem of childhood poisonings caused by ingestion of adult formulations of iron, either alone or in combination with multivitamins. We learned that, from 1986 to the present, over 40 children under the age of six died as a result of eating adult iron supplements - thus making iron the number one killer of children due to poisoning. Yet the bottles containing these products do not carry any warning to parents to let them know that iron can be highly toxic or fatal to their children. People treat these vitamin/mineral supplements as they would food, often leaving them uncapped and within easy reach of children, never dreaming that any harm could result. Yet, because these products are marketed as foods, they do not carry warnings about the dangers of overdose. This must be changed and we are currently addressing this problem.

In the area of health claims for dietary supplements, we strongly believe that supplements should be treated no differently from foods and should be subject to the same scientific standards of proof before being permitted to make a health claim. In our experience, manufacturers will often latch on to the most preliminary scientific developments and tout them as proven and conclusive facts to induce consumers to buy their products for their purported health benefits. These claims will then be passed on to supplement consumers as fit they were scientifically substantiated truths. In other cases, manufacturers have stretched the conclusions of scientific studies to apply to their own products when that application is not justified by the underlying science. For example, in enforcement actions we brought against Stresstabs and One-A-Day vitamins, the manufacturers deceptively claimed that scientific studies showed that their products could replace the vitamins and minerals lost through everyday stress. Their advertisements led people to believe that the ordinary stress of daily life results in the depletion of essential vitamins, and that these supplements could replace these lost vitamins. In fact, there is no scientific basis for a claim that emotional stress can deplete vitamins or that ordinary physical activity will result in such depletion.

The fact that we had reached an agreement with Lederle to stop making such claims did not stop Miles from making similar types of claims for its One-A-Day vitamins several years later. Those ads claimed that "Daily stress can chip away at your B vitamins and rigorous physical training can lower your body's supply of essential minerals. That's why One-A-Day vitamins are uniquely formulated to put back what your world takes away." There is simply no support for the claims that ordinary types of emotional stress and routine exercise deplete the body's supply of vitamins and minerals. These ads were yet another example of advertisers preying on consumers' interest in products that guarantee improved health. Had the NLEA's scientific standard requiring significant agreement among experts regarding the validity of a health claim been in place and applicable, it is unlikely that such a claim would ever have been made.

The National Association of Attorneys General, in a resolution passed at its summer meeting just a few weeks ago (a copy of which is attached), called upon Congress to insure that manufacturers of dietary supplements be held to the same standards as that

required of other food and drug manufacturers whose products are subject to the jurisdiction of the FDA under the Food Drug and Cosmetic Act. FDA must retain the authority to promptly remove potentially unsafe dietary supplements from the marketplace. Some of the legislation being proposed would make it more difficult for FDA to take action against dietary supplement products of questionable safety and efficacy. Any legislative proposal which shifts the burden to the underfunded and overworked FDA to prove that a supplement presents a substantial and unreasonable risk of illness or injury will result in consumers being subjected to unsafe products and unsubstantiated health claims for such products. The current law requires general recognition by experts of a product's safety and effectiveness or preapproval by the FDA prior to marketing a supplement for the cure and mitigation of serious disease. FDA's authority to stringently regulate such products should not be diminished.

The Attorney General does not oppose the availability of dietary supplements. From an enforcement perspective, however, we have seen firsthand that claims made by dietary supplement manufacturers have often been among the most misleading and confusing claims in the food industry. Freedom of choice exists for consumers only when the products are safe, any claims of nutritional benefits are true, and the product is not being marketed for a serious therapeutic or disease-related purpose without prior FDA pre-market approval. Moreover, dietary supplements must be properly labeled and should accurately reflect what the product contains, directions for use and precautions necessary to assure safe use. Of course, any claims that appear on the label must do so in a truthful and nonmisleading manner. Finally, all disease related claims must meet FDA's standards for such claims and be limited to those claims pre-approved by FDA.

Thank you once again for the opportunity to address the sub-committee on these important issues.