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Before the Committee on Governmental Affairs
Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia
United States Senate
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Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit this written statement. I am the President and Chief Executive Officer of Metabolife International, Inc. ("Metabolife"), which markets the nation's leading weight control dietary supplement -- called Metabolife 356®. I would like to take this opportunity to emphasize that my company strongly believes in the science supporting the safety and efficacy of dietary supplements that contain ephedra when used as directed, and also strongly believes that the Food and Drug Administration ("FDA") should issue a science-based regulation (consistent with laws and regulations issued in a number of states) that ensures that ephedra supplements are manufactured and marketed appropriately by all members of the dietary supplement industry.

At the outset, I wish to recognize the Ranking Minority Member of the Subcommittee, Sen. Voinovich, for his role in the Ohio law, which he signed as Governor. Ohio led the nation as its law provided the first comprehensive set of rules for ephedra-based supplements. The Ohio law protects pubic health and preserves the rights of consumers who use these supplements responsibly. Hawaii, Michigan, Nebraska, and Washington have followed Ohio with similar rules (and the Council of State Governments has also issued similar model legislation). As you know, a proposed rule to regulate ephedra-based supplements has been pending at the FDA for the last five years. We believe the American people would be well served if the agency promulgates a rule modeled after the Ohio law.

To date, we are aware of over 30 reports and studies (*See* Attachment A, which contains citations to representative reports and studies) supporting the safety/efficacy of products that contain ephedrine alkaloids - and we believe Metabolife 356® offers consumers a safe, effective way to satisfy their weight-loss objectives.

A recent report (September, 2002) issued by the Federal Trade Commission indicates that the majority of adults in the United States are overweight or obese, and that even the loss of a small amount of weight can prevent and improve many of the medical problems associated with weight gain. The FTC indicated that approximately 61% of U.S. adults are overweight or obese – and that overweight and obesity constitute the second leading cause of preventable death, after smoking, in the United States – resulting in an estimated 300,000 deaths per year.

We at Metabolife are proud that we are helping adult Americans address the important issue of weight loss. Consumers throughout the United States use ephedra dietary supplements as a safe, inexpensive, and effective manner in which to support weight loss, and leading obesity experts have publicly supported the use of these products. In fact, over the last five years, Metabolife has sold over 4.5 billion tablets, or approximately 50 million bottles, of Metabolife 356®.

Although we strongly believe in the safety and efficacy of our products, we are obviously quite sensitive to the concerns that have been expressed regarding the proper marketing and use of dietary supplements containing ephedra. We at Metabolife have been frustrated, however, that the favorable clinical research has been consistently ignored due to the inappropriate legitimacy placed upon anecdotal consumer call records. The General Accounting Office ("GAO") reviewed the "adverse event reports" that the Food and Drug Administration received from consumers, and determined that the reports were unreliable, inconsistent, and could not be used to determine causation. We believe the same logic would apply with regard to Metabolife's anecdotal call records.

The fundamental point is that anecdotal consumer call records cannot and should not substitute for well-controlled scientific studies. In the year 2000, the American Association of Poison Control Centers ("AAPCC") received thousands of reports on health problems associated with aspirin, acetaminophen, and ibuprofen. For example, it is our understanding that in that single year there were over 16,000 reports to the AAPCC involving aspirin, with over 5,000 reports of health problems and over 50 reports of death, over 56,000 reports involving acetaminophen, with over 9,000 reports of health problems and over 90 reports

of death, and over 57,000 reports involving ibuprofen, with over 7,000 reports of health problems and over 4 deaths. These data do not suggest any problems with the above products when taken as directed, and do not demonstrate causation. There is no reason to evaluate dietary supplements that contain ephedra any differently.

There should be no doubt that we strongly believe that properly manufactured dietary supplements that contain ephedra are safe when taken as directed on Metabolife's label. To our knowledge, there is not a single well-controlled clinical study that demonstrates that ephedra supplements are unsafe when taken as directed. In addition to the numerous, well-controlled clinical studies that support product safety, many other common-sense facts have been generally ignored in the controversy surrounding ephedra.

First, ephedra contains natural ephedrine alkaloids – and the FDA itself has approved the use of ephedrine in over-the-counter ("OTC") drug products (for asthma) without time limitation at daily dosages 50% higher than that contained in Metabolife 356®. Commonly used OTC drugs contain synthetic ephedrine, and the FDA has indicated that synthetic ephedrine is "generally recognized as safe and effective" at dosages of up to 150 mg/day. Consumers have been safely taking these asthma drug products throughout the past century, and still take these products today. Metabolife 356®, on the other hand, provides a maximum serving limit of 96 mg of ephedrine alkaloids per day.

Second, consumers have been taking drug products that contain synthetic ephedrine alkaloids along with caffeine throughout the past century, and continue to do so today. It has been reported that an average 16 ounce cup of coffee contains 300 mg of caffeine. Consumers with asthma have been safely ingesting coffee, along with ephedrine remedies, for years. Metabolife 356® contains approximately 40 mg of caffeine per tablet, and provides a maximum serving of 320 mg of caffeine per day.

Third, with millions of consumers ingesting any product, it is obvious that some of these consumers will experience health problems that occur widely in the general population. The FDA and HHS – supported by the GAO – have acknowledged that the existence of such anecdotal reports does not demonstrate a cause-and-effect relationship. With regard to ephedra, on June 14, 2002, Secretary Thompson indicated, in a letter to Public Citizen, that "the FDA has advised me that the types of observed outcomes reported in relationship to the ingestion of ephedrine alkaloids are not uncommon in the general population, and therefore the reports alone do not provide a scientific basis for assessing the safety of ephedrine alkaloids or establish a link between the reported adverse events and the ingestion of ephedrine alkaloids."

Fourth, contrary to what is repeated in news stories around the country, Metabolife has not released 14,700 "adverse event reports" to the FDA. Rather, we released anecdotal consumer call records that do not demonstrate causation, are inconsistent with the favorable background science, and are generally consistent with background levels of health problems in the population. Until the FDA defines the term "adverse event report" for the dietary supplement industry, we believe the term is inappropriate and should not be utilized.

Fifth, ingestion of ephedrine and caffeine for weight-loss purposes is not a new phenomenon. In Denmark, for example, consumers have safely used a weight-loss product (regulated as a drug under the Danish regulatory system) containing synthetic ephedrine and caffeine for the past 12 years.

The above common-sense facts, in conjunction with numerous well-controlled clinical studies, leads us to conclude that Metabolife 356® is safe when taken as directed on the product label. In fact, as part of its ongoing commitment to provide high-quality products to consumers, Metabolife has been: (1) actively monitoring the science surrounding ephedra and caffeine combinations, (2) committing to support the Department of Health and Human Services ("HHS") and the National Institutes of Health ("NIH") in their efforts to further research ephedra, (3) implementing quality assurance procedures (such as voluntary batch testing of each lot of product produced to ensure consistency with label claims) that far exceed those required by the FDA for dietary supplements, (4) taking affirmative steps to communicate that ephedra products are not for everyone and by informing consumers regarding proper use and stating that individuals with certain pre-existing conditions should consult a health practitioner prior to product use, and (5) actively pursuing stringent, science-based ephedra legislation, or regulation, to require all ephedra products to be marketed and manufactured responsibly and taken as directed.

Metabolife is aware of over 30 reports and studies supporting the safety/efficacy of products that contain ephedrine alkaloids (*See* Attachment A). Those studies include the recent Harvard/Columbia trial, a well-controlled, six-month study of 167 mildly to severely overweight adults. That trial found that the herbal combination produced only mild side effects, when compared to placebo, and that the data was consistent with the known mechanisms of action of ephedrine and caffeine and the

large number of studies conducted on synthetic ephedrine and caffeine. The study also demonstrated that the ephedra/caffeine combination was more effective than placebo in reducing body weight, body fat, and waist and hip circumference -- subjects in the ephedra/caffeine group lost an average of 11.7 pounds (5.3 kg) during the study, compared to an average of 5.7 pounds (2.6 kg) in the placebo group. (*See* Attachment B).

The scientific evidence, including the clinical trials and a comprehensive safety review conducted by Cantox Health Sciences International, supports the conclusion that properly manufactured ephedra dietary supplements are safe when taken as directed on Metabolife's label. Indeed, ephedra has been consumed safely worldwide for over 5,000 years. Moreover, as noted, FDA has previously found that synthetic ephedrine is "generally recognized as safe and effective" at dosages of 150 mg/day in over-the-counter ("OTC") drugs, such as asthma remedies, without time limitation.

Metabolife believes in ephedra's existing safety record. Moreover, Metabolife supports HHS's funding of the RAND Corporation to conduct a comprehensive review of the existing science on ephedra, and NIH for its intent to use the RAND study as a guide to expand research efforts on ephedra. To assist the government in these efforts, Metabolife has publicly committed to supporting, financially and otherwise, and urging others in the industry to support, a blue ribbon commission established by HHS or NIH to supervise one or more further long-term clinical studies of the safety and efficacy of ephedra/caffeine combinations for weight control.

In addition, Metabolife has taken proactive steps to ensure that Metabolife 356® actually contains what the label claims it contains. Despite the fact that Good Manufacturing Practices ("GMPs") for dietary supplements have yet to be issued, Metabolife has implemented quality control procedures, such as batch-testing, that exceed the GMPs for food. Metabolife's labeling also clearly states that the product should not be sold to minors; it recommends serving limits consistent with the levels that scientific studies have shown to be safe; and it has a stringent warning statement to advise people with certain pre-existing medical conditions against taking the product without consulting a health care professional. Moreover, Metabolife has committed, in its August 15, 2002, letter to Secretary Thompson, to prepare to lead an industry-wide consumer information campaign to warn against abuses of ephedra products, especially by young athletes and minors, and to urge all consumers to read the label carefully.

Unfortunately, although it is our understanding that many companies market products responsibly, ephedra supplements have been promoted to individuals, including minors, as street drug alternatives under such brand names as *Herbal Ecstacy, Black Beauties, Yellow Jackets, Herbal Coke*, *Magic Mushrooms*, and *Cloud 9*. We believe marketing dietary supplements as alternatives to "street drugs," or in ways that encourage abuse, is unacceptable. We call on the regulatory authorities to stop this outrageous conduct, and bring enforcement actions against such companies immediately. We also support the FDA for its recent actions against companies that sell dietary supplements that contain synthetic ephedrine alkaloids.

Because ephedra supplements are not for everyone, we strongly support a science-based, FDA regulation that would place limits on promotional claims, mandate serving limits, and generally require companies to act responsibly when manufacturing and selling their products. Accordingly, Metabolife has been advocating stringent, science-based ephedra legislation, or regulation, to require all ephedra products to be marketed and manufactured responsibly and taken as directed. Metabolife's proposal includes the following provisions:

- **Ban on Illicit Drug Claims –** Metabolife's proposal includes a prohibition on the promotion of ephedra products as alternatives to illicit drugs.
- **Ban on Sale to Minors** – Metabolife's proposal prohibits the sale of food and dietary supplements containing ephedra to individuals under the age of 18.
- **Ban on Synthetic Ephedrine Alkaloids –** Metabolife's proposal prohibits the sale of food and dietary supplements containing synthetic ephedrine alkaloids.
- **Mandatory GMPs** – Metabolife's proposal requires FDA to expedite GMPs for dietary supplements, and it requires manufacturers of ephedra dietary supplements to implement quality assurance programs, such as the batch-testing program already used by Metabolife, to ensure that ephedra products contain what they claim to contain.
- **Strict Labeling Statements –**Metabolife's proposal includes a strict warning statement providing that individuals with pre-existing medical conditions, such as heart or thyroid disease, should consult a physician or licensed qualified health care practitioner prior to product use.
- **Strict Science-Based Serving Limits –** Metabolife's proposal requires serving limits (up to 25 mg/serving and up to 100 mg/day) that are consistent with the results of a number of studies, including the Harvard/Columbia trial.

There is an emerging science-based consensus that these limits are safe among an increasing number of states (including Hawaii, Michigan, Nebraska, Ohio, and Washington). These states have already adopted ephedra legislation or regulations that incorporate these limits.

- **Mandatory Manufacturer Reporting to the FDA –** Metabolife supports mandatory industry-wide reporting to the FDA. In fact, to our knowledge Metabolife is the first and only dietary supplement company to voluntarily provide its consumer call records to the FDA.
- **Full Disclosure on Product Label –** Metabolife's proposal requires the labels on food and dietary supplements containing ephedra to disclose: (1) the amount of ephedra in each serving (and the amount of product that constitutes a serving), (2) that taking more of the product than recommended (or taking it at greater frequencies) may increase the risk of negative health experiences, and (3) that the maximum recommended daily dose of ephedra is 100 mg.
- **Consumer-Friendly Reporting –** Metabolife's proposal would require labels on food and dietary supplements containing ephedra to list a toll free number for consumer inquiries that is maintained by the manufacturer, distributor, retailer, or third-party. Alternatively, we support listing the FDA MedWatch number on product labels.

Finally, we at Metabolife would like to question whether it is good policy for the government to criticize a company for: (1) providing consumers with access to a voluntary help-line; and (2) voluntarily maintaining consumer call records. In establishing a voluntary help-line and maintaining these records, we engaged in unprecedented supportive actions for a dietary supplement company. We question whether any FDA-regulated company will ever again voluntarily maintain a help-line and maintain consumer records based upon the reaction we have received.

We thank you again for the opportunity to provide this information. Metabolife will continue to provide you and others with information like this that is based upon the best information available to us.