Response to Questions Posed
by the Committee on Governmental Affairs
Subcommittee on Oversight of Government Management,
Restructuring, and the District of Columbia

United States Senate
October 8, 2002

1. Please discuss the system that your company has in place to receive adverse event reports from consumers.

For purposes of clarification, there is no definition of "adverse event reports" in FDA regulations for the dietary supplement industry. There is confusion concerning whether this phrase refers to causation between use of ephedrine-containing products and the reported effects. To avoid any definitional confusion, we believe the more accurate term to describe Metabolife's records referred to herein is "call records," which are anecdotal in nature.

For years now, Metabolife has voluntarily operated a toll-free customer service line as a way to provide information to interested consumers regarding appropriate usage of the products. Eventually Metabolife's system became known as the Metabolife Health Information Line and it has been staffed for the most part by registered nurses. The Metabolife Health Information Line was not established as a means to collect consumer complaints or reported incidents. Rather, the line was a way Metabolife could provide information to interested consumers regarding appropriate product usage. Call records are therefore varied in nature, as information was written on, among other items, calendars, sticky-pads, blank paper, and established forms. The system put into place by Metabolife, consistent with its purpose, was neither intended nor designed as a means to collect consumer complaints or reported incidents. Many of these records are incomplete and inconsistent. See also our response to Question No. 6, below, regarding our support for a national mandatory reporting system.

When consumers raised a health issue that they claimed required medical attention, Metabolife's practice was for the nurses or other health information representatives to advise the caller to see his or her physician if they hadn't already. If the consumer stated that they had already consulted a physician, Metabolife's general practice was and is for the nurse or other health information representative to ask the consumer to provide medical documentation regarding the claimed issue. Metabolife would send the caller, or in some cases the caller's health care practitioner, a medical release form that would allow Metabolife to receive and review the caller's medical records. Metabolife received medical records from callers in approximately 40 - 50 instances. The records were reviewed, and a medical doctor was also generally consulted regarding the records received.

2. Please advise the subcommittee of the qualifications of the Metabolife staff who have answered the health line since your company's inception.

See our response to Question No. 1 above. Currently, the Health Information Line is staffed by 3 registered nurses.

3. Please describe the training or guidance that Metabolife provides staff who are taking consumer calls with respect to the management of symptoms.

The Health Information Line staff has been instructed to become familiar with Metabolife's products and the recommended usage of such products consistent with the product's comprehensive label instructions, scientific information including published clinical trials of ephedrine containing products, and to incorporate this information into their overall health knowledge.

4. The Subcommittee is also interested in hearing about any follow-up actions that your company has undertaken to investigate any of the serious health effects that some of your consumers report having

experienced while using your product.

See response to Question No. 1 above.

5. Prior to this year, how many adverse events had Metabolife shared with the Food and Drug Administration?

Until its voluntary production this year, Metabolife has not shared its call records with the FDA. See also our answer to Question No. 6, below.

6. Why has Metabolife in the past been so adverse to sharing this information with FDA?

In the context of litigation, Metabolife considered inappropriate FDA's efforts to obtain the call records in one lawsuit in which there was a court-ordered confidentiality agreement which applied to both plaintiff and Metabolife. As the court stated in its ruling upholding this confidentiality order:

> The FDA has a statutory obligation to protect the health of the general public through the regulation of products intended for human consumption. The confidentiality agreement in this case, however, has no legal relevance to the investigatory duties of the FDA. If consumer complaints were imperative to the FDA's duties, then Congress would have provided the FDA with the power to obtain such information. Indeed, Congress expressly provided the FDA with the ability to obtain consumer complaints regarding prescription drugs, but withheld this authority in regards to dietary supplements. Additionally, the GAO report (citation omitted) criticizes the FDA for its dependence upon consumer complaints in its proposed rules pertaining to dietary supplements. There is no evidence to support a finding that the FDA's interest is prejudiced or injuriously affected by the confidentiality agreement.

Having said that, Metabolife retained three experts to evaluate these call records in preparation for disclosure of these records publicly with the only exception being protecting the individual identities and personal information of the callers because of legal and other privacy obligations. As you know, subject to those privacy considerations, all of these records were turned over to your staff and the FDA – along with the reports of the three experts.

Given that there is no law or regulation requiring dietary supplement companies to report anecdotal call records, Metabolife has been under no obligation to do so. To repeat, we did so voluntarily – because we believed it might assist in the crafting of a nationally imposed mandatory reporting system, applicable to dietary supplement companies, administered by the FDA and if necessary by Congressional action. We look forward to working with FDA and Congress to achieve that objective.

7. Your company has now turned over 14,700 adverse event reports to FDA, but they are in a format that precludes the FDA from performing any follow-up because contact information is withheld from the agency. When other companies provide FDA with adverse event reports, they do so in unredacted format. Why is Metabolife resisting providing the agency with information in a form that would allow for appropriate investigation?

As outlined in our August 15, 2002 letter to Secretary Thompson, we are willing to try to work out some basis for providing personal information regarding our consumers consistent with privacy and other possible privilege issues. At present, the format of the production is dictated by privacy considerations and laws that we believe protect callers from public disclosure of their private information. We have indicated in our letter to Senator Durbin dated August 29, 2002, that we are prepared to provide this unredacted information as long as we obtain assurance that Federal and state privacy laws and considerations would not be violated.

See also our response to Question No. 6 above.

8. How many personal injury cases have been filed against Metabolife? How many consumers do these cases represent? How have these cases been disposed of? How many have been settled? How many are outstanding? What is the total dollar amount that Metabolife has paid out or agreed to pay out in settlements to those claiming to have been injured by Metabolife's product? Of the cases settled, how many are sealed and thus unknown to the public?

Over the years, there have been approximately 145 personal injury cases filed against Metabolife in State Superior and Federal District Courts. To the best of our knowledge, these cases represent approximately 160 consumers (not including several cases with undefined groups of plaintiffs). Of these cases, approximately 9 have been dismissed, one was granted summary judgment, approximately 29 have been resolved, and there are approximately 100 active cases.

We are not able to disclose the terms of individual settlement agreements because we are bound by confidentiality obligations entered into by the respective plaintiff and Metabolife, many of which were requested by either the plaintiff or insurance companies. However, we can state that over the years approximately five million dollars has been paid in personal injury cases mostly by insurance carriers.

9. What research has your company done to evaluate the safety of its product?

To date, we are aware of over 30 reports and studies supporting the safety and/or efficacy of products that contain ephedrine alkaloids - and we believe Metabolife 356® offers consumers a safe, effective way to satisfy their weight-loss objectives. In addition to relying upon opinions of world-renowned experts, Metabolife has conducted extensive scientific literature review, commissioned laboratory tests, and has funded clinical studies. The published safety and/or efficacy clinical trials funded in all or in part by Metabolife include:

- Harry Gwirtsman, M.D., An Ephedrine, Caffeine & Chromium Compound Acutely Increases Energy Expenditure in Healthy Obese Adults, 7 (1 Supp.) Program Abstracts, NAASO Annual Meeting (Nov. 1999) (abstract).

- Carol N. Boozer, et al., An Herbal Supplement Containing Ma Huang-Guarana for Weight Loss: A Randomized, Double-Blind Trial, 25 Int'l Journal of Obesity 316 (2001).

- Carol N. Boozer, et al., Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial, 26 Int'l Journal of Obesity 593 (2002).

10. Does your company support a ban on sale of ephedra-containing products to minors?

Yes.

11. Please tell the committee the medical conditions a consumer might have that would make the consumer a poor candidate for an ephedra-containing product?

The Metabolife 356® label clearly states that women who are pregnant or nursing should not take the product.

In addition, the Metabolife 356® label clearly advises consumers who have, or have a family history of certain conditions such as heart disease, thyroid disease, diabetes, high blood pressure, recurrent headaches, depression, any psychiatric condition, glaucoma, difficulty urinating, enlarged prostate, seizure disorder, are using any prescription drug, a Monoamine Oxidase Inhibitor (MAOI) or any other dietary supplement, prescription drug or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolanine (ingredients found in certain allergy, asthma, cough/cold and weight loss products) to consult with their physician or health care professional before taking the product.

12. Does your company believe that ephedra-containing products should only be taken under the supervision of a doctor?

As the Metabolife 356® label states, we advise consumers to consult with a physician or licensed health care professional if they meet the criteria identified on the label.

13. What other measure would your company support to provide greater safety to consumers of ephedra-containing products?

· Ban on marketing of ephedra-containing products as illicit drugs

· Ban on sale to minors

· Ban on use of synthetic ephedrine alkaloids in dietary supplements

· Good manufacturing practices (GMPs) - Including a requirement that manufacturers of dietary supplements 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 - Including a strict warning statement providing that individuals with pre-existing medical conditions 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.

· Full disclosure on product label – Labels on food and dietary supplements containing ephedra should be required 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.