

EMERSON RESPONDS:

On January 18th, *Tainted Supplements: Where do they come from?* aired on Dr. Oz show as part of his Tainted Supplements vs. the FDA series. The conclusion of the show was that there is a large, unscrupulous and profitable part of the “dietary supplement industry” that traffics in such products, making extravagant claims to consumers, such as promising rapid weight loss, without regard to, or interest in, public health or safety. We have provided our expert opinion. We hope that this allows you to become more informed about the issues so that you are able feel increased confidence in the products you recommend to patients.

We always encourage you to make an appointment to speak with one of the on-staff physicians to discuss any additional concerns or questions.

Thank you for choosing Emerson Ecologics.



January 18, 2012

Tainted Supplements vs. the FDA – Dr. Oz series

On January 18th, *Tainted Supplements: Where do they come from?* aired on Dr. Oz show as part of his Tainted Supplements vs. the FDA series. **As a part of this story, members of Dr. Oz staff went undercover and discovered that five out of five weight-loss supplements that they bought tested positive for sibutramine**, an ingredient in prescription obesity drugs that was banned because it caused heart attacks, strokes and seizures. In addition, one of the five tested positive for the antibiotic ciprofloxacin (Cipro). The Dr. Oz show reviewed these findings and, with guests Jim Kababick of Flora Labs and Peter Cohen of Harvard Medical School, raised some significant concern regarding spiked dietary supplements. The conclusion of the show was that there is a large, unscrupulous and profitable part of the “dietary supplement industry” that traffics in such products, making extravagant claims to consumers, such as promising rapid weight loss, without regard to, or interest in, public health or safety.

FDA regulation

While the issue of spiked and therefore adulterated dietary supplements is a serious one that merits attention, it is important to keep this issue in perspective. First, in contrast to the belief held by many, **dietary supplements are federally regulated under 21 CFR part 111. These regulations prohibit product adulteration.**

While the FDA enforces 21 CFR Part 111 and the dietary supplement industry has several ways in which they self-regulate, there are still some ‘bad actors’ that do not follow the regulations and have escaped federal and industry scrutiny. This situation exists in part due to insufficient resources on the part of the FDA to regularly inspect all dietary supplement manufacturers. **Of note, the FDA has stepped up its auditing activities over the past couple of years and has successfully identified several of these unscrupulous manufacturers.** It is also true that supplements do not require pre-market approval, but rather are regulated once they are in the marketplace. At that point, the FDA’s job is to identify and remove dangerous products from the market.

Emerson Ecologics safeguards

Emerson Ecologics has reduced the likelihood of carrying products spiked with pharmaceutical drugs due to several safeguards that we have in place. These include:

1. **We stay current with industry adulterants and adulterated products** and avoid carrying these high risk products.
2. **We review all labels of new products for any suspicious or exaggerated claims or ingredients.** This is particularly true for products in the categories of weight loss, muscle building and sexual enhancement.
3. **We require certificates of analysis for products that we have identified as being at risk for containing spiked ingredients.** We periodically verify these certificates of analysis at one of our independent qualified laboratories.



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4. **We have established the Emerson Quality Program (EQP) which provides our customers with an added layer of credibility** to the already reputable professionally recognized lines of products that we carry. The EQP validates participating brands' quality via a rigorous quality review that includes document audits, on-site audits and product analytical testing at qualified independent labs. Upon successful completion, the participating brand is noted by a seal as an EQP Partner, EQP Silver Partner, or EQP Gold Partner.

- **The EQP Partner** has demonstrated rigorous raw ingredient and supplier qualification processes, and analytical testing for identity, purity and potency that is compliant with the dietary supplement regulations, 21 CFR Part 111.
- **The EQP Silver Partner** meets the qualifications of Partner and additionally demonstrates the use of the most accurate and sensitive testing methodologies for all purity tests, and conducts full potency testing of active ingredients in finished products using risk-based skip lot testing.
- **The EQP Gold Partner** meets the qualifications of the Silver Partner and ensures that each lot of finished products have been fully tested for all adulterants and contaminants, has a real time stability program in place to verify the expiration date, and has evidence of environmentally sustainable practices and product research and development.

Through all of these activities, Emerson has provided its customers with several layers of added quality assurance. Visit our quality page (emersonecologics.com/quality) to learn more about the EQP and the quality practices of our EQP partners.

