

Tainted Supplements and The FDA



Learn how the FDA is working to keep supplements tainted with harmful, illegal and sometimes deadly substances off of store shelves.

Added to [Articles](#) on Mon 01/16/2012

Recently, producers of *The Dr. Oz Show* went undercover and discovered how easy it was to buy tainted supplements the FDA has recalled. *The Dr. Oz Show* then sent the supplements for lab testing. All five weight-loss supplement samples came up 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 a powerful antibiotic called ciprofloxacin (Cipro). **This is believed to be the first time that traces of this powerful antibiotic have been found in an over-the-counter supplement.**

The Dr. Oz Show alerted the FDA about this new development. Here is the response from the FDA's Office of Public Affairs:

"This is the first time we've heard of contamination of a dietary supplement with Cipro. We would be very, very interested in seeing your data so that we can follow up. [*The Dr. Oz Show*] asked whether this would trigger an investigation. It's difficult for us to say exactly how we'd proceed; we would start with looking at the evidence and go forward from there.

We have been quite proactive in going after these tainted dietary supplement cases, and we have cited about 300 of them just in the last couple of years. [In December 2010, we also called on industry to take action as well.](#)

Part of the challenge is finding the source of the product. The packaging frequently contains no contact information for the manufacturer, or perhaps the name is only of a sub-level distributor. In cases where we do have a distributor name, we can take action, but there may be many other distributors still marketing the product.

We go at this with a two-pronged approach: We engage our Office of Criminal Investigation to try to track down the source, and we provide information to consumers so that they can arm themselves with ways to avoid these products. Consumers should be wary of products that make claims that sound too good to be true or that claim to work 'just like' an approved drug. Labeling that is all in a foreign language is also suspicious.

We also find that many consumers don't understand that dietary supplements are not regulated in the same way as drugs. With minor exceptions, companies that want to bring new drugs to market have to provide extensive safety, effectiveness and marketing data to FDA and receive an approval before they can market the drug. FDA does not have the authority to require that they present data to demonstrate that the supplement is safe or effective. The only premarket control we have is that manufacturers do have to notify (not get approval from) us if they plan to use a New Dietary Ingredient (NDI) and provide a basis for why they feel that the supplement containing the NDI is safe. However, we've only received about 700 of those and it's estimated that there are more than 55,000 products on the market.

Ultimately, FDA bears the burden of proving that a supplement is *unsafe* to remove it from the marketplace. In order to do that, we must exhaustively test the product, which is pretty resource-intensive.

Dietary supplement manufacturers are not required to register their products with FDA, so we have no conclusive way of knowing exactly how many products are out there. That said, we are constantly monitoring the marketplace looking for products that are likely to be in violation, either because they contain an active pharmaceutical ingredient or because their labeling claims to cure, treat, prevent or mitigate disease.

The current Good Manufacturing Practice (GMP) requirements for dietary supplements went into effect in 2008 and were phased in based on the size of the company over three years. As of June 2010, all dietary supplement manufacturers are subject to the current GMPs. Among other requirements, companies have to have standard operating procedures for verifying the integrity of their ingredients, which generally eliminates the 'I didn't know it was in there' defense. Just in the last two weeks, we've taken action against two dietary supplement manufacturers based on current GMP violations."