Dietary supplements: Manufacturing troubles widespread, FDA inspections show

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Federal inspections of companies that make dietary supplements — from multivitamins and calcium chews to capsules of echinacea and bodybuilding powders — reveal serious and widespread manufacturing problems in a $28 billion industry that sells products consumed by half of all Americans.

In the last four years, the U.S. Food and Drug Administration has found violations of manufacturing rules in half of the nearly 450 dietary supplement firms it has inspected, according to agency officials.

The inspection reports portray an industry struggling to meet basic manufacturing standards, from verifying the identity of the ingredients that go into its products to inspecting finished batches of supplements.

Some firms don't even have recipes, known as master manufacturing records, for their products.

Others make their supplements in unsanitary factories. New Jersey-based Quality Formulation Laboratories produced protein powder mixes and other supplements in a facility infested with rodents, rodent feces and urine, according to government records. FDA inspectors found a rodent apparently cut in half next to a scoop, according to a 2008 inspection report.

"It's downright scary," said Daniel Fabricant, head of the FDA's Division of Dietary Supplement Programs. "At least half of industry is failing on its face."

The FDA began conducting inspections in 2008 to assess compliance with new regulations governing the manufacturing, packing and holding of dietary supplements. Since then, 1 in 4 dietary supplement companies inspected by the agency have received a warning letter, considered a significant enforcement action.

So far this year, FDA inspectors have found violations of good manufacturing practices during two-thirds of the 204 inspections they have conducted in nearly 200 supplement firms' facilities, agency officials said. Seventy of these inspections resulted in the agency's most serious rating.

Cara Welch, vice president of scientific and regulatory affairs for the Natural Products Association, a large dietary supplement trade group based in Washington, D.C., called the inspection numbers "unfortunate" and a significant issue her organization has been tackling.

"We can't give up on the industry," Welch said. "We are going to make it as strong as can be."
Manufacturers large and small are making significant efforts to implement the regulations, including sections borrowed from the FDA's drug manufacturing rules, said Michael McGuffin, president of the American Herbal Products Association, a trade association based in Silver Spring, Md.

But it takes time for companies to come into compliance with such a large and complex set of rules and for the FDA to establish how the rules will be enforced, McGuffin said. "Not everybody was in compliance on the day the rule was passed, but that is not uncommon in any rulemaking," he said.

Fabricant disagreed. The final rule was published in 2007. "You can get a lot done in five years," he said.

Underscoring the importance of the issue, some customers have suffered serious health problems linked to companies' poor manufacturing practices.

In 2008 more than 200 people — including a 4-year-old — were poisoned by selenium after taking liquid multivitamin dietary supplements that were sold in health stores and by chiropractors, according to a medical paper published on the mass poisoning. The products, called Total Body Formula and Total Body Mega Formula, contained an average of 40,800 micrograms of selenium per serving instead of 200, according to the paper.

John Adams, of Chipley, Fla., was one of the victims. His silver hair — which had earned him the nickname "Silvertop" at work — began falling out in clumps. His fingernails and toenails became discolored, peeled off, regrew and peeled off again. He had a hard time remembering how to do his job as a telephone repairman. He became so weak it was hard to get in and out of his work truck, and eventually he was forced to retire.

Adams and his wife, who also experienced problems, sued along with dozens of others. This year, the couple received a settlement. Adams, now 65, said he is still weak on his left side, has ruined fingernails and toenails that do not grow and struggles with memory problems.

"What is a person in America to do to be healthy?" Adams wrote in an email. "Who can you trust? Not the supplement industry because it does not take long for a tainted product to make you very sick."

Rod Cate, attorney for Total Body Essential Nutrition, the distributor of the products, wrote in an email that his client had been in business for more than 10 years with no problems and with satisfied customers before the companies that manufactured Total Body Formula produced the tainted bottles.

In his opinion, Cate wrote, the problem was caused by contractors incorrectly interpreting the formula, incorrectly formulating it, or both. The company is in the midst of settling lawsuits, he wrote.
"Not sure if FDA inspections of manufacturing facilities would have made any difference as this was a problem with formulation and not a problem with the manufacturing facilities themselves," Cate wrote.

Fabricant called the Total Body Formula incidents "a classic case" of not adhering to good manufacturing practices. "This is why these things are important," he said.

Unlike drug companies, dietary supplement firms are not required by law to prove to the FDA that their products work or are safe before they sell them. The FDA does regulate the claims that firms make about their products — for example, companies cannot say a supplement will cure a disease — and the agency can take action if it deems a product to be an imminent hazard or significant risk.

The FDA also can regulate the way supplements are made, and in 2008, the agency began enforcing its new rules through inspections of the largest of the industry's nearly 1,400 supplement firms. Medium-sized and small firms were given a year or two longer to comply.

A flurry of warning letters soon followed, along with more serious consequences like legal action against companies and their owners.

In the case of the Paterson, N.J., supplement plant infested with rodents, the federal government filed a civil complaint against Quality Formulation Laboratories, related companies and their owner in 2009. The defendants agreed to stop manufacturing and distributing their products and to meet a series of conditions before starting up again.

Instead, according to the government, the defendants simply moved their production to another plant in Congers, N.Y., even providing transportation to the facility for employees. Last year, a jury found the defendants guilty of multiple counts of criminal contempt, fining the companies and sentencing the owners and managers to prison time. The convictions are being appealed.

Bradford Williams, manager of the FDA Division of Dietary Supplement Programs, expressed exasperation while addressing an audience at SupplySide West, a large dietary supplement conference in Las Vegas in October.

"It doesn't seem that the firms are getting it," Williams said. "How do I reach this industry? Do I have to use nuclear bombers to do it?"

McGuffin's response: "I understand from (Williams') point of view he wants it all to be perfect right now. But that's not the real world." Other industries have experienced steep learning curves — with similar or worse violation rates — when government introduces new regulations, he said.

"I don't excuse the industry for not being prepared, but I would expect there would be a higher level of out-of-spec issues on that first go-round," said Steve Mister, president of the Council for Responsible Nutrition, a dietary supplement and ingredient supplier trade association based in Washington, D.C. "In many cases, the companies are learning as the inspector is there."
Fabricant said the FDA's rules are basic and often cover practices — like ensuring the finished product matches specifications — that should have been in place long ago. Warning letters typically are sent after firms fail to fix problems identified in earlier inspections, he said.

In one typical example, an Eden Prairie, Minn., company called Milk Specialties Global got an FDA warning letter in December after an inspection of its plant in Wautoma, Wis. According to the letter, the plant did not establish specifications for finished batches of some supplements — such as what exactly should be in the products.

The agency also said the company kept incomplete records of its batches of supplements and failed to record how it makes decisions when changes are made during the production process.

In a statement, Milk Specialties Global spokeswoman Amy Rotenberg wrote that the company takes quality assurance and compliance with federal regulations very seriously. After getting the warning letter, the company sent the FDA detailed information about how it is complying with the rules.

"Milk Specialties is committed to continuing its ongoing best practices of manufacturing products of the highest quality and will continue to work cooperatively with the FDA," Rotenberg wrote.

The big worry, Fabricant said, is that lax controls by dietary supplement makers will cause a public health catastrophe.

In 2006, an ingredient mix-up killed more than 200 people in Panama and left many more sickened or disabled. In that tragedy, a Panamanian government pharmaceutical company failed to verify that a sweet syrup from China was glycerin, the ingredient it had ordered, according to a World Health Organization report.

It wasn't glycerin, the report said — it was diethylene glycol, a poison. Testing the identity of the ingredient would have revealed that.

ConsumerLab.com, an independent group based in White Plains, N.Y., has been unearthing problems with commercial dietary supplements through laboratory testing for a dozen years.

About 1 in 4 products the company tests have a significant problem, said Tod Cooperman, president of ConsumerLab.com.

Some contain significantly less of an ingredient than is promised on the label, some far more. Sometimes the product contains contaminants, like lead. Some are rancid. Some have the correct ingredients but are "bedpan bullets" — incorrectly formulated pills that won't break up in the body.

The problems turn up in products from companies large and small, fringe and mainstream, Cooperman said.