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‘Recipe For Disaster’ In Supplement Manufacturing? US DoJ Attorney Cooks Up Likely Causes

by Malcolm Spicer

> "You end up with a recipe for maybe there's adulterants in the product. Maybe the product wasn't manufactured according to the spec, so it's misbranded. Worse, there could be adulterants. In some of those ingredients, there's a lot of potential failures,” says Patrick Runkle, senior litigation counsel at DoJ Consumer Protection Branch, during FDL conference.

Signs pointing to a dietary supplement firm potentially crossing regulatory lines often come in multiple steps creating “a recipe for disaster,” a federal prosecutor suggests.

Patrick Runkle, a senior litigation counsel at the Department of Justice Consumer Protection Branch, speaking at a recent regulatory conference, also advised firms marketing supplements in the US to have documentation affirming suppliers’ and other third parties’ compliance with Food and Drug Administration regulations.

The “sort of chain of events that we see sometimes and from some surprisingly large companies,” Runkle said, often starts with someone “who maybe isn't the best choice to be designing supplements due to their lack of knowledge.”

“Or maybe there’s prior involvement in illegal conduct related to the FDA. That person is the one running the company and they designed some sort of pre-workout something – that’s step one.”

Step two can come in hiring a third party to make a product and take care of ingredient supplies because the marketer can’t afford to also conduct manufacturing.

"So, then they go to third-party manufacturers, somewhere, somewhere out of state, somewhere hundreds of miles away. They rely on the support and expertise of that third-party contract manufacturer, who says, 'Everything's fine, I'll get all these ingredients for you, I'll put all this together. I'll make your pills out of it. I'll label it, it will be your label, everything will be fine'," Runkle said.

"That first person, the supplement company principle, hasn't done a whole lot of homework as to whether this manufacturer knows what they're doing, whether it also has regulatory problems or compliance problems; has never set foot inside that facility, maybe has no idea."

US FDA Supplement Facility Inspection Numbers Back To Typical Along With GMP Problems Found

By Malcolm Spicer

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Supplement facility GMP inspections by FDA in 2022 along with the frequency of form 483s sent to firms following inspections return to roughly pre-pandemic annual numbers after dipping during 2020 and 2021.

Read the full article here

'A Lot Of Potential Failures'

A marketer may not have made sure of its supply chain, which under the best of circumstances "can be problematic," Runkle added.

"You have the supply chain piece where either the supplement company principal or the third-party manufacturer is kind of cutting corners or is trying to bring in ingredients ... from overseas suppliers that don't adequately test each batch. Some of the batches are not even testable because they are odd botanical ingredients and there's no real standard. Testing would be expensive anyway, which is another issue," Runkle said.

"What you end up with is a recipe for failure. You end up with a recipe for maybe there's adulterants in the product. Maybe the product wasn't manufactured according to the spec, so it's misbranded. Worse, there could be adulterants. In some of those ingredients, there's a lot of potential failures."

Food and drug law attorneys with clients in the supplement sector exhibiting those practices should steer them toward compliance instead.

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> *"Some batches are not even testable because they are odd botanical ingredients and there's no real standard. Testing would be expensive anyway, which is another issue." – Patrick Runkle, DoJ Consumer Protection Branch*

Runkle acknowledged that the FDA's regulatory oversight of supplement manufacturing, labeling and marketing " kind of works a lot of the time" and "it's not all gloom and doom."

"But we have seen issues and we've seen some importers engaged in conduct like smuggling a product and under a different name. That may not have even been illegal in the first place, but they thought would be easier to get it in and then the product turns out to have a whole lot of lead and they don't realize that until they send it out to a manufacturer who actually tested it. Then they have to do kind of a silent recall and of course FDA can't find out about it because the stuff was smuggled in the first place," he said.

Runkle spoke on 23 March at a Food and Drug Law Institute conference in Washington with online access available. *(Additional HBW Insight reporting from the conference is linked in related articles above and below.)*

Documentation Helps Industry As Well As Regulators

Runkle also acknowledged that marketers and other firms which intend to be fully regulatorily compliant can incur problems from businesses in its supply chain. Documentation of compliance, while always important, becomes necessary to protect against potential regulatory problems.

"My pitch for that always has been and continues to be that internal documentation, good internal documentation helps industry much more than it hurts industry. It helps. It helps honest players be able to point to documentation that says 'Hey, we did the right thing.' And at the very least, that helps us identify who the real bad actors might be. That's one thing that helps," he said.

"If you have a retailer or a manufacturer who's selling a product that ultimately turns out to be adulterated with something bad, and they have done the right thing by getting these guarantees down the line, they've done some testing,

US FDA's Infant Formula Regulatory Authority Doesn't Reach 'All That Needs

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we're not going to be streaming in there with federal agents usually," he added.

Runkle noted the settlement GNC Holdings Inc. agreed to in 2016 following an FDA and DoJ investigation of the firm's supply chain practices as a model for documenting suppliers to ensure regulatory compliance. (Also see "*GNC Supply Chain Reform Pays Dividends In DoJ Settlement From DMAA Investigation*" - HBW Insight, 7 Dec, 2016.)

To Be Fixed'

By Malcolm Spicer

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"This system is fundamentally prone to supply chain disruptions with so few manufacturers," says Mark Moorman, FDA Office of Food Safety director. In FDLI presentation, he acknowledges delicate balance in stemming distribution of potentially contaminated power formula while sustaining supply.

Read the full article here

The "non-prosecution agreement" required GNC to pay $2.25m to the federal government, though DoJ didn't identify the payment as a fine, but resolved the firm's liability for selling USPlabs LLC's supplements formulated with the stimulant DMAA, or 1,3 dimethylamylamine. (Also see "*DoJ Prosecutions: USPlabs Guilty, DMBA Firm Indicted From FDA Investigations*" - HBW Insight, 14 Mar, 2019.)

The agreement required GNC, since acquired by Chinese firm Harbin Pharmaceutical Holding Group Co. LLC , to cooperate in the DoJ's prosecution of USPlabs LLC and executives from the firm on criminal charges stemming from engaging in a conspiracy to import ingredients from China using false certificates of analysis and false labeling and lying about the source and nature of the ingredients after using them in its products.

The agreement imposed requirements that generally track manufacturers' responsibilities under FDA's 2007 supplement good manufacturing practices final rule while putting the firm on higher alert to detect and prevent violations.

The agreement, which also required GNC to commit an additional $500,000 to the industry guidelines initiative, was set to be effective for 60 months but allowed the firm to request early termination after 36 months.

"Part of the idea behind that non-prosecution agreement was to encourage industry to generate more internal documentation and more representations, both from the retailer in the retailer space and the manufacturers space," Runkle said.

"GNC agreed, essentially to obtain more specific guarantees from … manufacturers and suppliers. They were going to be getting your specific signed guarantees from those manufacturers and suppliers, from control people at those companies related to the ingredients

and related to the compliance of the supplements."

The FDA's supplement GMP final rule emphasizes documentation at every step. When the agency warns supplement manufacturers and marketers about GMP violations, failing to fulfill one more documentation requirements almost always is noted. (Also see "*Supplement GMP Documentation Better, But Still No. 2 On FDA Observation List – AHPA*" - HBW Insight, 23 Dec, 2019.)