

Sunland Suspension Shows FDA On Hunt For Serial Violators

By Greg Ryan

Law360, New York (November 27, 2012, 8:45 PM ET) -- The U.S. Food and Drug Administration suspended a food producer's registration for the first time ever Monday when it shut down beleaguered peanut products maker Sunland Inc., reassuring companies wary of the agency's new powers that it will reserve them for repeated violations, not isolated recalls or outbreaks.

The FDA was granted the ability to revoke a company's food facility registration by the Food Safety Modernization Act, signed by President Barack Obama in January 2011. Before the law was enacted, the agency had to obtain a court order prohibiting a company from selling its products.

The agency's citation of Sunland's spotty safety record, including a salmonella outbreak that has sickened at least 41 people across 20 states, should help assuage companies' uneasiness about how the FDA would use its suspension authority, attorneys told Law360.

There have been larger, deadlier foodborne illness outbreaks since the FSMA was enacted, but the agency only leveled a suspension when it had strong reason to believe a company's products would continue to endanger the public, attorneys said. During inspections of Sunland's plant in September and October, the FDA found that surfaces in manufacturing and production areas were contaminated with salmonella.

"For your average food company, it should not be a cause for serious alarm. This doesn't mean the FDA's going to come in on routine inspections ... and start suspending companies' registration," Faegre Baker Daniels LLP partner Sarah Brew said.

The agency suspended Sunland's registration after the company's peanut products were linked to the salmonella outbreak. Sunland voluntarily recalled almond and peanut butter products in late September, and it expanded the recall in October after FDA inspectors uncovered safety violations at its facility.

The FDA mentioned the outbreak, as well as Sunland's history of food safety violations, in its decision to suspend the registration. Sunland's own testing records show the presence of salmonella in 11 lots of nut butter from 2009 to 2012, portions of which were distributed to consumers, according to the agency.

Sunland's reaction to the FDA's findings also likely played a role in the agency's suspension decision, according to attorneys. The company vehemently denied it had ever distributed products it knew had the potential to be contaminated.

"With the company disputing whether they knowingly shipped the product or not ... I don't think the FDA felt comfortable allowing this plant to operate," Marler Clark LLP managing partner Bill Marler said.

Sunland told the FDA earlier in November that it would take action to address the agency's concerns, but the company failed to include important details about the nature of those actions, leaving the FDA unable to determine whether they would be effective, according to the agency.

Had the company sufficiently addressed the FDA's concerns in its response, the agency would likely not have suspended its operations, attorneys said.

"Usually, the company says, 'Gee, I'm really sorry, we're now going to spend tens of millions of dollars updating our plant,' and after a period of time the FDA allows them to start operating," Marler said.

The FDA may have also used the suspension of Sunland as a warning to other companies or for political reasons, according to attorneys.

"One might speculate they chose to go after a small company in such a big way to address criticisms that they're only going after the larger companies. It might be important for them politically to be seen as having gone after a smaller company," Perkins Coie LLP partner Lawrence Reichman said.

Under the suspension, Sunland cannot introduce food into commerce. The suspension can only be lifted if the FDA determines the company has implemented procedures that ensure safe products. The company can ask for an informal hearing with the agency to review the suspension.

Sunland shut down operations at its peanut butter plant before it issued the recall. It sent the FDA a letter on Nov. 20 saying it planned to resume operations on Monday, but the agency decided to suspend its registration that day. The company had "expected that any agency concerns with its plans would be part of the ongoing dialogue with the agency," it said.

"This really demonstrates that a recall isn't enough if the FDA doesn't have confidence the company has implemented rigorous preventative controls to prevent something like this from happening in the future," Brew said.

--Additional reporting by Sean McLernon. Editing by Elizabeth Bowen and Jeremy Barker.

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