Homeopathic Teething Company Can't Dilute Violations Found By FDA

By Julianna LeMieux — September 14, 2017

For some time, we have been covering the investigation into the practices used to produce the homeopathic teething products that allegedly caused illnesses and deaths of infants. Most recently, we wrote about a warning letter sent from FDA to Raritan Pharmaceuticals [2] - one of the companies that sold the products - that listed multiple violations found in their facility.

A letter was also sent to Homeolab - the Canadian company that manufactures the powder blend mixtures that are used by Raritan for making the teething products. As a result of an inspection, significant violations were found at the site.

The most important violations concerned the lack of testing or confirmation of the products sent to Raritan, which were to be put into the teething products. Whatever was sent to Raritan and later into the teething products is anyone's best guess.

FDA cited a lack of control procedures to monitor the processes used to make the products. Not surprisingly, the drugs were tested and found to be non-homogenous in composition. In addition, the manufacturing instructions are not well specified.

Perhaps even more disturbing than the lack of proper protocols and resulting guesswork about what the company is producing is how the company was not forthcoming with some information.

For example, FDA writes that the "consultant impeded the inspection by preventing our investigator from photographing this piece of equipment." It's a big red flag when a company delays, denies, limits or refuses an inspection.

Something else that smelled fishy was the bait and switch game that Homeolab tried to play on the
FDA. There are, in fact, two company names - Homeolab USA, Inc. and the parent company Homeocan, Inc. - for one company, very likely to ensure there is always one company to place the blame onto. The response from the companies states that "Homeolab is NOT a manufacturer. Homeolab is a private label distributor, which has no manufacturing capabilities" and that "Homeocan is by agreement a contract manufacturer for Homeolab."

Please. Did they really think that the inspectors at FDA wouldn't see through this?

It did. The FDA's response:

"Homeolab USA Inc. and Homeocan Inc. share the same address, facility, and personnel, including the chief executive officer and the head of quality. Your head of quality signs email correspondence with “Homeocan Inc./Homeolab USA” as your firm’s identity. Homeolab (part of the parent company, Homeocan Inc.) is a registered manufacturer with the FDA. According to your Duties and Responsibilities document, Homeolab is responsible for “GMP Compliance with regulatory bodies” and “Approval of Batch for Distribution.” In terms of drug manufacturing, Homeolab USA Inc. and Homeocan Inc. have no significant separation, so we are treating Homeolab/Homeocan as a single entity."

There is now evidence of multiple violations that led homeopathic companies to produce and distribute something that was truly an unknown. And, the worst part about this (and why I feel compelled to keep writing about it) is that then well-intentioned parents bought products that they should not have been buying and put them in their infant's mouths and bodies.

If this does not make people question what they are buying when they choose something homeopathic, I'm not sure what will. When will people stop defending an industry that won't let FDA take photos of their facilities and hides behind two different company names to avoid responsibility?


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