

INDUSTRY application

Gemini favors plant-based excipients to propagate clean-label supplements

Gemini Pharmaceuticals, Commack, NY, is a contract manufacturer of OTC pharmaceuticals and nutritional supplements. The company specializes in solid dosage products and makes more than 15 billion tablets and capsules annually.

Working in the dietary supplement industry requires Gemini to stay abreast of consumer trends, said Mike Finamore, Gemini's chief executive officer. One of the biggest trends is "clean-label" products, a development he and colleagues foresaw a few years ago.

"From our place in the industry, we saw that eliminating pharmaceutical inactive ingredients was going to be a very strong piece of our nutritional industry in the future," he said. "Between some activist websites and certain influential people, there were voices drawing attention to these manufacturing agents or excipients. Traditionally, these were not even looked at by the customer."

Magnesium stearate, a lubricant widely used in tablets and capsules in very small amounts, was among the excipients under fire. Flow aids and other processing agents were also deemed suspect, even though they've



Gemini Pharmaceuticals was among the first to incorporate plant-based, organic excipients into its customers' dietary supplements. The company produces more than 15 billion tablets and capsules annually. The photo shows a V-type blender at its plant in Commack, NY.

been used safely for decades. "Magnesium stearate and other pharmaceutical inactive ingredients have their purpose in pharma and nutrition, and their characteristics have been perfected over time," Finamore said. But whether the excipients had value in a manufacturing sense didn't

The company has developed more than 500 products using the alternative ingredients.

matter. Customers wanted something else, and the question became, "What can we do to eliminate these things in our supplements yet still have the characteristics required to manufacture a product?" Finamore said. Through friends, he discovered Ribus, based in St. Louis, MO, which offers alternatives.

Rice hulls as starting material

"Ribus had these really unique ingredients that they were bringing to market," Finamore said. One of the first was Nu-Flow, which is made from sterilized rice hulls ground to a fine powder. That process allows the naturally occurring silica in the hulls to provide functionality in solid dosage formulations. As a result, formulators can replace anti-caking agents such as silicon dioxide and tricalcium phosphate with a natural and certified organic ingredient.

In September 2016, Ribus introduced Nu-Mag, a superior replacement to magnesium stearate than its predecessor, Nu-Rice. Nu-Mag is a blend of rice extract, rice hulls, gum arabic, and sunflower oil. It provides lubrication similar to that of stearic acid and allows manufacturers to use a label statement that reads "rice extract blend." It's also certified organic.

Finamore said that using the ingredients in existing products requires some effort because it's not always a one-for-one swap. "We prefer engineering products from the ground up using the suite of Ribus materials when possible because it gives us better predictability and allows us to create some interesting nutritional products," he said. "It also allowed us to introduce our customers to a new product development pipeline. Once our customers have the confidence in the Ribus items through our expertise—and see the value-added of using them—we are usually asked to go back and re-engineer existing items," he said. "Our partnership with Ribus certainly has offered us a point of differentiation as a contract manufacturer."

He estimates that Gemini has developed more than 500 products using the ingredients. "We've probably introduced more Ribus ingredients into finished products than any other manufacturer. We certainly have more products in the marketplace using the Ribus family of products than any other manufacturer." Gemini was the first company to be named a Ribus certified contract manufacturer.

Super-clean labels: No inactives

"Initially there was some resistance because of the unknowns, but now [customers] are much more open to us suggesting novel materials, alternative formulations, and different ingredients than they were 2 years ago," Finamore said. "We can eliminate traditional inactive ingredients without sacrificing the quality or efficacy of the formulations." The cost premium of the ingredients hasn't been a problem, either. "Ribus material is little more expensive than traditional excipients, but it's not the predominant cost driver in any product we're using. So that objection was overcome by simply showing our customers the engineering and marketing benefits."

Finamore said it's not clear whether alternative excipients will appeal to manufacturers of OTC drug products. "I'm not sure how

many people looking to buy ibuprofen are curious about how it's made. In certain cases, it might be an opportunity." He said functional foods, alternative remedies, and condition-specific supplements look to be a better fit. "There are unbelievable growth opportunities for alternative inactive ingredients such as those offered by Ribus."

In fact, they can sometimes be listed in the label claim. "We've done that in some cases where customers want an absolutely clean product. For instance, we're able to incorporate the Ribus ingredients into the supplement facts as an actual nutrient-carrying ingredient," Finamore said. "That means the inactive ingredients outside the supplement facts panel become nonexistent. It's super-clean to design a label that way, and we and others are taking advantage of that. It's challenging to design a product and label that way, but it also satisfies our customers' demand for a cleaner label product because everything in there has a functional purpose." T&C

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