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The sun rises on sterols

By Dale Buss & Julian Mellentin

North American sterol manufacturers believe that the Food & Drug Administration's move last month [February] to allow them to make health claims for sterols on a wider range of foods and beverages will begin a significant acceleration of their ingredients into the marketplace and a rapid increase in consumer acceptance of sterols as an effective counter to heart disease.

While the FDA has yet to issue a final rule, the agency energized the sterols industry by finally acceding to manufacturers' requests to make heart-health claims for sterol-containing foods other than the spreads and salad dressings that the regulators approved three years ago.

The dam broke when on February 14 when Cargill Inc. received a letter from the FDA that the company is interpreting as a de facto endorsement of its petition to make a health claim for sterols as ingredients in more categories of food products than the agency now allows. Soon after the agency issued a similar letter to Forbes Medi-Tech Inc..

For the last couple of years, spreads and salad dressings such as Benecol and Take Control have been OK-ed by the agency to make a heart-health claim. For the last several months, the agency had been making it clear to every interested party that it hadn't already issued a final rule on heart-health claims for other foods including sterols/stanols - some 18 months after issuing the interim rule - in large part because it was resource-constrained. After the September

11, 2001, terrorist attacks, more FDA resources flowed to food safety concerns.

FDA CHOOSES ENFORCEMENT DISCRETION

Barbara Bentson, Cargill's director of regulatory safety and quality systems, told *New Nutrition Business* that, though Cargill understood the pressures on the agency, the company had pressed the FDA to wink at an expanded health claim for sterols on an interim basis. "Using 'enforcement discretion'

"I believe that these
margarine-like spreads, in fact,
will eventually become only a
small part of the market for
sterol-based foods"

would allow consumer-packaged-goods companies to put products into the marketplace that the agency already knows are safe and effective products," she said.

What the agency actually said in its February 14 letter to Cargill is, "FDA intends to consider the exercise of enforcement discretion, pending publication of the final rule, with respect to certain requirements of the health claim," as long as the foods in

question meet certain criteria such as including at least 0.65 grams of phytosterol esters or 0.4 grams of free phytosterols per serving."

The agency also noted in its letter that "the final rule may differ from the broadened criteria [just issued, and] manufacturers would then be required to change their labels to conform to the final rule".

But the Minneapolis-based grain giant didn't mince words when interpreting the agency's cautious language as "[providing] a unique and immediate opportunity for the food industry" to incorporate Cargill's sterols into "new heart-healthy commercial products."

NEW PRODUCT LAUNCHES EXPECTED THIS YEAR

Minneapolis-based Cargill immediately introduced the brand name CoroWise for its phytosterols, which it intends to help food processors introduce in breads, cereals, beverages and other new products. Vancouver-based Forbes said that new types of sterol-based dairy products and a "designer" oil will likely be coming out this year. Archer Daniels Midland Inc., based in Decatur, Ill., said that sterol-based nutrition bars manufactured by some of its customers should hit the market in 2003.

Sterol producers also said it was significant that the FDA blessed both foods employing free sterols as well as those using sterol esters, which combine sterols with a

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