

Danone to resubmit bolstered article 13.5 dossiers

By Shane Starling, 22-Sep-2009

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Danone will resubmit withdrawn article 13.5 European Union probiotic health claims by year's end with additional trials added to the dossiers to strengthen their claims, according to a health claims expert working with the company.

Studies such as one published this month in the *British Journal of Nutrition* that showed gut health benefits among a healthy population of women would boost Danone's claims, said Cédric Bourges-Sevenier, general manager of the French consultancy, Nutraveris.

"The three withdrawn claims will be resubmitted by year's end," Bourges-Sevenier told NutraIngredients.com in a discussion about health claims. *"Danone has some new studies onboard and they will strengthen its case."*

Danone head of vice president of external affairs and head of EU regulatory affairs, Patrick O'Quin, last week said the company was on the brink of resubmitting claims but first wanted to see European Food Safety Authority (EFSA) guidance stemming from its June stakeholders meeting.

An [EFSA](#) spokesperson could only say that guidance would be published "soon".

Danone was unavailable for comment at the time of publication.

Additional backing

The *British Journal of Nutrition* study should add to the strength of Danone's gut health argument that is central to two of its three article 13.5 claims relating to its spoonable probiotic yoghurt, Activia.

It showed gastro-intestinal well-being was improved by about 70 per cent in about 200 women with mild intestinal discomfort when they consumed Activia fortified with *Bifidobacterium lactis* DN-173 010-containing .

To read NutraIngredients.com's coverage of that study click [here](#) .

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Danone's other withdrawal was an [immunity](#) claim for the drinking yoghurt, Actimel, for which Bourges-Sevenier said other studies were close to completion.

Generic opionions

Bourges-Sevenier said the [probiotics](#) industry was waiting for the publication of the first batch of article 13.1 generic claims, which was likely to include some of the 300 or 400 probiotic strains on the list, due by the end of September.

But he said many of the claims were being withdrawn because they were too specific to lie on the generic list and were to be resubmitted on the article 13.5 list, especially in the case of probiotic blends.

He said a similar situation was occurring in regard to a number of herbal products owned by clients of Nutraveris, which has advised on more than 20 health claim dossiers.

Danone's US arm, Dannon, completed an out of court settlement yesterday in which it agreed to remove the word "immunity" from on-package marketing from its DanActive drinking yoghurt product.