

November 18, 2009

INGfertility Distributor and Wholesale Accounts

Re: Wrongful actions of our competitor/false and misleading information

Dear Colleagues:

I am writing to clarify a situation regarding INGfertility's products Pre~Seed® and Pré® which are sold in your territory. As you know, Pre~Seed® and Pré® are the first, and currently only, products cleared as Class 2 devices by the United States Food and Drug Administration (FDA) with claims of "safe to use when trying to conceive" and "intended for use during fertility interventions." This unique regulatory designation is based on stringent FDA review, lot release testing, as well as ongoing stability testing of the products. Please rest assured that all of INGfertility products are tested above and beyond the FDA requirements before they are sold.

Moreover, INGfertility also performs routine stability testing at different times after production to make sure each product retains its properties in accordance with specifications throughout the product's shelf-life. Any assertion that INGfertility does not do so is false and misleading. Contrary to assertions made by a competitor, none of INGfertility products have been the subject of a safety recall.

As evidence of INGfertility's diligence, in late 2008 INGfertility undertook a voluntary product withdrawal of a particular batch of Pré® product. This was done when preliminary stability testing on a lot of Pré® raised a possible non-safety concern (no Pre~Seed® was involved). INGfertility, in an abundance of caution, chose to contact its customers for return of relevant Pré® while it conducted confirmation tests. This was not an FDA recall enforcement action, as falsely stated by the competitor on the Internet. Moreover, as INGfertility reported to the FDA in January 2009, the final testing results showed that the initial voluntary product withdrawal was unnecessary because confirmation tests showed that the product was within specifications at all times and offered no public health risk.¹

¹ Notwithstanding the lack of a need for a withdrawal, INGfertility confirmed that no Pré® product in the batch that was the subject of INGfertility review remained in commerce after October 2008.

The wrongful actions of our competitor violate INGfertility's United States federal trademark rights, state false and misleading information that disparages INGfertility's Pré® and Pre~Seed® products in violation of United States and international laws, and violate other applicable federal and state laws. We have taken action to inform the competitor of the wrongful nature of its action and are prepared to exercise all legal options necessary to ensure only accurate and truthful information is disseminated. It is our objective to ensure that this wrongful activity on the part of our competitor does not extend to your regulatory agency.

Sincerely,



Dennis Clifton
CEO & President