



January 31, 2019

Dear Healthcare Provider,

As a valued partner, we wanted to inform you that Alfasigma USA, Inc. and VSL Pharmaceuticals, Inc. are involved in an ongoing business dispute with Claudio De Simone and his affiliated company, ExeGi Pharma LLC, regarding the probiotic VSL#3[®]. Despite what you may have heard, VSL#3[®] can and will continue to be commercialized under its current brand and name. The product will remain available to patients and is still available in retail pharmacies around the world.

The purpose of this memo is to address some inaccurate and misleading allegations you may have recently heard regarding the dispute. These false allegations are being circulated by individuals who stand to gain financially and reputationally from the spread of misinformation around the marketplace. Regrettably, much of this misinformation has been disseminated without any disclosure of conflicts of interest.

It is true that a jury in the U.S. District Court of Maryland, in November 2018, returned a verdict finding Alfasigma USA, Inc. liable for false advertising under the Lanham Act. However, De Simone and ExeGi Pharma mischaracterized the verdict. Indeed, ExeGi's website recently acknowledged that its recent published statements reflect only ExeGi's claims in the lawsuit, and not specific findings established by the court. **To be perfectly clear, the verdict contained no specific findings concerning the quality, production, efficacy or safety of VSL#3[®].**

Alfasigma USA, Inc. is vigorously contesting, along with the other defendants in this case, the jury's verdict and in particular the finding that it engaged in any false advertising. We assert that the evidence presented at trial did not support the verdict issued, and in turn, have submitted post-trial motions to set aside or modify the verdict.

In mid-2016, the manufacture of VSL#3[®] was moved from a manufacturing facility operated by Danisco in the United States to a facility in Italy. This change was announced to the public at the time. Information about this change, including the location and equivalence of the manufacturer of VSL#3[®] has been publicized and is readily available to consumers, health care providers and academics.

Evidence introduced at trial, which included testimony from one of the world's most preeminent scientists in the field of microbiology and probiotics, showed that the current Italian-made VSL#3[®] contains bacteria that is equivalent to the VSL#3[®] previously manufactured by Danisco. Experts and scientists who worked on VSL#3[®] when it was originally made in Italy in the 1990s and early 2000s confirmed that:

- I. **Italian-made VSL#3[®] contains the same 8 strains** of bacteria as the product manufactured by Danisco;
- II. **Italian-made VSL#3[®] is equivalent** to the Danisco product; and
- III. Studies previously performed on the Danisco product can be relied on to show the efficacy and safety of the Italian-made product.

Earlier studies were performed on the product manufactured by the facility in Italy. A genomic characterization was performed on the 8 strains in VSL#3[®].¹ Additional clinical studies are currently being conducted and will be published upon completion. VSL Pharmaceuticals is committed to continuing its investments in scientific research.

Patient health has always been, and will continue to be, the driving-mission behind the probiotic VSL#3[®]. If you have any questions or concerns, or you would like more information, please visit www.vsl3.com or contact us at info@alfasigmausa.com.

¹ Douillard FP, Mora D, Eijlander RT, Wels M, de Vos WM (2018) Comparative genomic analysis of the multispecies probiotic marketed product VSL#3. *PLoS ONE* 13(2): e0192452. <https://doi.org/10.1371/journal.pone.0192452>