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About CYSTARAN™'s Manufacturing Delay

In September 2010, the U.S. Food and Drug Administration (FDA) issued a complete response letter to Sigma-Tau Pharmaceuticals, Inc. for CYSTARAN™ (cysteamine hydrochloride ophthalmic solution), a therapy for the treatment of corneal cystine crystals in patients with cystinosis. The final approval has been delayed to allow the third party manufacturer of CYSTARAN™ to meet additional standards of production requested by the FDA. While the FDA's questions about manufacturing are impacting the timeline for product availability, Sigma-Tau Pharmaceuticals, Inc. is committed to the cystinosis community and is diligently working to reach the final stage of the product's approval process. For more information regarding CYSTARAN™ and its pending FDA approval, please contact Lesli King at lesli.king@sigmatau.com.