Hugel Aesthetics Receives FDA Acceptance of BLA Resubmission for LetibotulinumtoxinA for Injection for Glabellar Lines

PDUFA goal date set for April 6, 2023

NEWPORT BEACH, Calif.--(BUSINESS WIRE)-- Hugel America, Inc. (Hugel Aesthetics) announced today the acceptance of its Biologics License Application for letibotulinumtoxinA, by the U.S. Food and Drug Administration (“FDA”). The FDA considered the resubmission a Class 2 response and has assigned a April 6, 2023 action date per the Prescription Drug User Fee Act (PDUFA).

Jim Hartman, President of Hugel Aesthetics, stated, “We have worked diligently to advance our regulatory submission of letibotulinumtoxinA. With this notice from the FDA, we remain focused on a U.S. commercial launch in mid-2023. We look forward to providing an update on the status of our application per our PDUFA date of April 6, 2023, while continuing the development of our commercial strategy for letibotulinumtoxinA.”

About Hugel Aesthetics

Hugel Aesthetics is a division of the global medical aesthetics leader, Hugel, Inc., focused on commercializing a synergistic aesthetic portfolio in the United States, Canada, and Australia.

Hugel Aesthetics is dedicated to making aesthetics more attainable for all. For more information, visit: www.hugel-aesthetics.com

Kayleigh Adam,Alison Brod Marketing Communications, kayleigh@abmc-us.com

Source: Hugel America, Inc.