Mylan
Seeing
is believing

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VIA EMAIL & FEDERAL EXPRESS

Captain Valerie Jensen
Associate Director
Drug Shortage Staff
Center for Drug Evaluation and Research
Food and Drug Administration
W0 22, Room 6204
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Your August 26, 2014, Letter Regarding Haloperidol Lactate Injection Sent Pursuant to Section 506C(f) of the Federal Food, Drug, and Cosmetic Act

Dear Captain Jensen:

We are responding to your August 26, 2014, letter, which seeks an explanation as to whether FDA was notified, pursuant to Section 506C of the Federal Food, Drug, and Cosmetic Act, of any interruption in Agila Specialties Private Limited's ("Agila") manufacture of Haloperidol Lactate Injection occurring sometime between December 2013 and May 2014.

By way of background, Agila has an approved ANDA to manufacture Haloperidol Lactate Injection at its SFF facility. Following the issuance by FDA of a Warning Letter regarding the Agila SFF facility in September 2013, Agila stopped distribution and limited manufacturing of products from that facility, including Haloperidol Lactate Injection. At that time, Mylan had not yet acquired Agila but began working cooperatively with Agila to address the Agency's concerns. Mindful of the impact that the actions necessary to address the Agency's concerns would have for drug shortage products, Mylan proactively initiated communication with the Agency, prior to its December, 2013 acquisition of Agila, to identify the drugs manufactured at Agila with possible shortage concerns, including Haloperidol Lactate Injection. Additional information was provided shortly thereafter in response to an inquiry from Dr. Aldridge, when Agila confirmed that a number of products, including Haloperidol Lactate Injection, would be impacted by the Warning Letter and the ensuing remediation. Following those initial communications, Mylan sought to establish an avenue for ongoing communications with the Agency regarding drug shortage products and shared detailed information regarding the status of all approved products at Agila sites, in order to facilitate a productive dialogue between the company and FDA to address all potential shortage issues.

As you may recall, Agila expedited the testing and release of product batches that had been placed on hold at SFF in the fall of 2013. Notwithstanding the limited manufacturing and distribution of products from the SFF facility during the remediation period following receipt of

the FDA Warning Letter, Agila manufactured six additional batches of Haloperidol Lactate Injection in November 2013, January 2014, and February 2014, and released these for distribution to the U.S. market through April 2014. No additional units were manufactured after that date. Agila has not taken additional orders from customers since May 2014.

To the extent that any miscommunication or misunderstanding between Agila, Mylan, and FDA may have occurred with regard to Haloperidol Lactate Injection, it was unintentional and we take the Agency's recent communication most seriously. Mylan and Agila value the cooperative working relationship we have established with FDA and are committed to open and transparent communications with the Agency regarding potential drug shortage concerns. The bi-weekly calls with FDA's Drug Shortages Program that resumed last week will further enhance these communications by providing a forum for discussing potential drug shortage issues and prioritizing manufacture of shortage drugs. We are also further enhancing our internal processes across our product portfolio to ensure we continue to meet the Agency's expectations of an open and early dialogue.

Mylan reaffirms its commitment to assisting FDA, as it has in the past, to mitigate drug shortage concerns. Mylan has a deep and unwavering commitment to drug quality, integrity and reliability. We also have the highest respect for FDA, its mission, and its processes. Our continuing goal is to ensure that all Agila facilities meet the highest quality standards so as to supply high quality injectables to help address drug shortages in the United States.

Most immediately, as we have discussed, we are committed to addressing any shortage for Haloperidol Lactate Injection and are working to accommodate manufacturing of the product. In addition, within the next 10 days (by October 6, 2014) we will provide FDA with an updated and complete list of the status of the products at Agila sites to better enable us to work cooperatively with FDA to address all shortage concerns in a comprehensive fashion.

Thank you for your consideration of this response.

Sincerely yours,

Martina O'Sullivan, B.Sc. (Hons) Dip. Reg. Aff., MTOPRA
Senior Director of Regulatory Affairs