RESPONSE TO PREA NON-COMPLIANCE LETTER

October 30, 2015

Dr. William Dunn, M.D.
Director, Division of Neurology Products
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Attn: Taura Holmes (Regulatory Project Manager)

RE: sBLA 125274/S-102, Sequence 0219
Cross Reference BLA/STN 125274/0, BLA 125274/1 and
Cross Reference IND 106959
DYSPORT® for Injection (abobotulinumtoxinA)for Injection, 500 and 300 Unit vials
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Dunn:

Reference is made to the BLA 125274/S102 **NOTIFICATION OF NON COMPLIANCE WITH PREA** sent by the FDA to Ipsen on August 23rd 2015 which noted that Ipsen had not submitted a pediatric assessment for PMR-2933-1 which was deferred until August 1, 2015. The Agency was therefore notifying Ipsen that due to the failure to submit either a pediatric assessment or a request for a deferral extension, Ipsen was not in compliance with federal law.

Reference is made to the submission by Ipsen on August 10th (Sequence 0215) to BLA 125274/0 and BLA 125274/1 that responded to the BLA 125274/0 and BLA 125274/1 **MISSED MILESTONE POST MARKETING REQUIRMENT/COMMITMENT** letter from the FDA released July 14th 2015. Ipsen informed the FDA in this communication that it planned to submit the study report for 2933-1 (PMR#1) by the end of 3Q15/beginning of 4Q15 as part of a sBLA for treatment of lower extremity spasticity in cerebral palsy patients.

Reference is made to the submission by Ipsen on September 30th (Sequence 0218) of the sBLA for the indication for treatment of lower extremity spasticity in cerebral palsy patients. Included in this submission was the final study report required to fulfill PMR-2933-1 (PMR#1).

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Given the above communications from Ipsen to the FDA on August 10th (prior to the August 31 2015 deadline) that informed the Agency that PMR 2933-1 would be submitted late 3Q/early 4Q 2015, and its subsequent submission on September 30th 2015 of the study report to satisfy PMR 2933-1, Ipsen considers it has met and fulfilled the PREA requirements and requests the Agency consider withdrawal of the September 23 2015 PREA NON COMPLIANCE LETTER

As requested by the FDA NOTIFICATION OF NON-COMPLIANCE WITH PREA letter, Ipsen is submitting this letter to the sBLA 125274/102, cross referencing BLA 125274/0, BLA 125274/1and IND 10695. A copy of this letter will be sent to CDER, Division of Pediatric and Maternal Health (DPMH).

Should you require any additional information, please contact me at 908-400 4306 or at gerard.hickey.ext@ipsen.com.

Sincerely,

Gerard Hickey M.V.B. PhD
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Cc: CDER Division of Pediatric and Maternal Health (DMPH)