



NDA 022524

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Midatech Pharma US Inc.
Attention: Mary Kay Delmedico, PhD
Vice President, Scientific & Regulatory Affairs
8601 Six Forks Road, Suite 400
Raleigh, NC 27615

Dear Dr. Delmedico:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Zuplenz (ondansetron) oral soluble film, which was approved on July 2, 2010.

The Agency has determined that you have failed to meet the postmarketing requirements (PMRs) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMRs 1664-1, 1664-2, 1664-3, and 1664-4, which were deferred until July 31, 2017 (2), September 30, 2017, and June 30, 2018, respectively. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a “**DEFERRAL EXTENSION REQUESTED**” in your response.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a “**RESPONSE TO PREA NON-COMPLIANCE LETTER.**” To facilitate our review, submit this information to your NDA with a cross-reference letter to the Investigational New Drug Application (IND) to which your protocol has been submitted.

If you have any questions, call Mary Chung, PharmD, Senior Regulatory Project Manager, at (301) 796-0260.

Sincerely,

{See appended electronic signature page}

Lisa M. Soule, MD
Associate Director
Division of Gastroenterology and Inborn Errors
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LISA M SOULE
08/06/2018