Worldwide Safety & Regulatory
Pfizer Inc
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Worldwide Safety & Regulatory

21 July 2017

Theresa Michele, M.D., Division Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Food and Drug Administration
Center for Drug Evaluation and Research
c/o Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

RE: NDA 201803, Advil® (ibuprofen sodium, 256 mg) Tablets
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Michele:

Reference is made to NDA 201803 for Advil (ibuprofen sodium) tablet, 256mg; the Agency's "Deferral Extension Granted" correspondence dated March 12, 2014; (b) (4) 1905-1 and the June 12, 2017 "Notification of Noncompliance with PREA" letter.

Cross reference is also made to IND 105341 under which the studies were conducted.

The original approval Letter for NDA 201803, states that final study reports in fulfillment of the pediatric assessment requirements under PREA are to be submitted to NDA 201803 with the designation "**Required Pediatric Assessment(s).**" Pfizer completed the required postmarketing study 1905-1 and subsequently submitted the final study report to the NDA on May 1 2014, in advance of the June 30, 2014 deadline as stated in the Agency's Deferral Extension Granted letter dated March 12, 2014.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this response or wish to discuss or meet regarding this program, please contact me via email at Michael.Bailey@pfizer.com or phone at 973-660-5373.

Sincerely,

Michael Bailey
Head of Regulatory Affairs, North America & Rx-OTC Switch
Pfizer Consumer Healthcare