DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**
Division of Freedom of Information
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857

October 08, 2015

Parents Against Pharmaceutical Abuse (PAPA)
ATTN: Andrew Thibault
11828 Castine Street
New Port Richey, FL 34654

Re: Thibault v. FDA, Case No. 8:15-1813-Y-36TGW

Dear Mr. Thibault,

Enclosed is the second set of records that FDA is providing to you in accordance with FDA's Second Unopposed Motion to Enlarge All Deadlines, which the Court granted on September 28, 2015 in the above-referenced case. These documents are responsive to FOIA request number 2014-8101, which was for specific FDA Adverse Event Reports.

Specifically, these records consist of 711 Adverse Event Reports, which total 2,994 pages. Because FOIA request 2014-8101 was for a large number of records, the records have been divided into three groups (Parts A, B, and C). These documents have been redacted in accordance with the Freedom of Information Act, 5 U.S.C. § 552, and other applicable laws. The following 10 Adverse Event Reports, which were listed in FOIA request number 2014-8101, no longer appear in FDA's Adverse Event Report System and thus cannot be retrieved: 3781563, 3849378, 3910658, 4094531, 4147944, 4157501, 6208895, 6199016, 6215850, and 7576491. Additionally, FDA has determined that the following 12 Adverse Event Reports appear twice in your FOIA request: 6526177, 5872820, 8767227, 6351526, 6445569, 7794328, 7979016, 8409912, 8497070, 8649545, 8664151, and 8723946.

Charges of $691.00 (Search $690.00, Review $, Reproduction $, Computer Time $, CD $1.00) will be included in a monthly invoice. The total may not reflect final charges for this request.

Thank you for your time and attention to this matter.

Sincerely,

Howard Philips
Deputy Director
Office of Regulatory Policy
Division of Information Disclosure Policy

Enclosure: Medwatch Cases (1 CD)