March 21, 2017

The Honorable Michael Burgess, Chairman
U.S. House of Representatives
Energy and Commerce Committee, Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green, Ranking Member
U.S. House of Representatives
Energy and Commerce Committee, Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess & Ranking Member Green:

The Epilepsy Foundation strongly supports the reauthorization of the Food and Drug Administration's (FDA) user fee programs and commends the Energy and Commerce Subcommittee on Health for moving the PDUFA agreement forward in the subcommittee. The Epilepsy Foundation is committed to accelerating the development and approval of new therapies, especially to benefit those in our community with difficult to control seizures and those who experience significant side effects from existing therapies. We support a strong FDA that is responsive to the needs of the patient community and the innovations of scientific research and health care delivery. We urge Congress to move judiciously through the process of reauthorizing the user fee programs and to honor the negotiations that led to the agreements.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 3 million Americans with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions.

The ability of the FDA to properly evaluate and approve therapies so they can enter the market in a timely manner is critically important to the Epilepsy Foundation because of our interest in and need for medical innovation. While many significant advances have been made in epilepsy over the past several years, including the development of innovative medications, medical devices, and surgical options, unfortunately, the number of people with epilepsy who are still experiencing seizures, despite being treated for the condition, has not changed. Today, 1 in 26 Americans will develop epilepsy in their lifetime; however, there is no cure, and even with many drugs and treatment options, one third of people with epilepsy live with uncontrollable seizures. Uncontrolled seizures can lead to disability, injury, and even death. Innovation is of importance to the people with epilepsy for whom available treatments do not work, as well as all Americans living with complex chronic and rare conditions that are not appropriately managed with current treatment options.

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These user fee agreements are the result of many years of discussion with all relevant stakeholders, including the FDA, industry, and the patient community. The policies and goals included in the agreements reflect what these stakeholders value and will help ensure advancements and improvements within the FDA and ultimately health care more broadly.

The Epilepsy Foundation applauds congressional and agency leadership for this agreement that will continue the trajectory of patient-centered innovation at the FDA. If you have any questions or concerns, please contact Angela Ostrom, Chief Legal Officer & Vice President Public Policy at aostrom@efa.org or 301-918-3766.

Sincerely,

Philip M. Gattone
President & CEO
Epilepsy Foundation