May 17, 2017

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

Dear Chairman Burgess and Ranking Member Green:

The Epilepsy Foundation strongly supports the reauthorization of the Food and Drug Administration’s (FDA) user fee programs and commends the House Energy and Commerce Committee, Subcommittee on Health for moving the agreements forward. The Epilepsy Foundation is committed to accelerating the development and approval of new therapies, especially to benefit individuals 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 encourage you to honor the process that led to the user fee agreements and to pass the FDA User Fees Reauthorization Act as negotiated without changes to funding levels or additional amendments involving peripheral issues that should themselves be granted full and independent consideration.

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.

Promoting biomedical innovation and bringing promising therapies to market sooner is exceptionally important to the epilepsy community because no cure exists for epilepsy and one third of people with epilepsy live with uncontrollable or intractable seizures – and many more live with debilitating side-effects from medications. Despite the development of innovative medications, medical devices, and surgical options over the past several years, the number of people with epilepsy who are still experiencing seizures has not changed.

The FDA plays a key role in advancing medical innovation – the agency must be able to properly evaluate and approve therapies so they can enter the market in a timely manner. The user fee programs help to facilitate this process. The 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.

Innovation is important to not just people living with epilepsy but for all Americans living with complex chronic and rare conditions that are not appropriately managed with current treatment options. The Epilepsy Foundation applauds congressional and agency leadership on these agreements 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, M.Ed.
President & CEO
Epilepsy Foundation