



## FDA User Fee Agreements PDUFA, MDUFA & GDUFA

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**Position:** The Epilepsy Foundation supports the reauthorization of the Food and Drug Administration's (FDA) user fee programs. These programs must be reauthorized this year to ensure that the FDA can sustain its important work and continue to develop and refine its processes to get more valuable therapies to the market in a timely manner. 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.**

**About Epilepsy:** 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.

**Background:** 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. Currently, no cure exists for epilepsy and one third of people with epilepsy live with uncontrollable or intractable seizures. Uncontrolled seizures can lead to disability, injury, and even death. Innovation is of particular 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.

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.

**If you have any questions or concerns, please contact Angela Ostrom, Chief Legal Officer & Vice President Public Policy at [aostrom@efa.org](mailto:aostrom@efa.org) or 301-918-3766.**