



March 7, 2007

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs
Food and Drug Administration (FDA)
5630 Fishers Lane
Room 1601
Rockville, MD 20852

**RE: Expanded Access to Investigational Drugs for Treatment Use
Food and Drug Administration (FDA)
Department of Health and Human Services (DHHS)
Docket No: 2006N-0062
RIN: 0910-AF14**

Dear Dr. von Eschenbach;

The National Association of Epilepsy Centers (NAEC) appreciates the opportunity to comment on the Food and Drug Administration's recent proposed rule: *Expanded Access to Investigational Drugs for Treatment Use (21 CFR Part 312)* published in the Federal Register on December 14, 2006. NAEC is a non-profit trade association whose members include more than 100 specialized epilepsy centers across the United States. Founded in 1988 by physician leaders committed to setting a national agenda for quality epilepsy care the group educates private and governmental policymakers and regulation about appropriate patient care standards, reimbursement issues and medical services policies.

As advocates for epilepsy patients and their providers we applaud the FDA's efforts to clarify and expand the circumstances in which patients not enrolled in drug clinical trials may nevertheless be provided the drug prior to approval. The regulations, if adopted, will decrease barriers facing patients' access to experimental drugs. We especially appreciate the clear guidelines as to when individual access will be granted and the explicit explanation of criteria that must be met by the requestor.

Definition of Immediately Life Threatening

The first criteria for participation in the expanded access program is that a patient's condition must be life threatening. Based on the information the requestor has provided the FDA must determine that the patient (or patients) to be treated has a serious or immediate life threatening disease or condition. In the proposed rule the FDA does not define serious but does define immediately life threatening as: "a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment." The FDA is requesting comments on this proposed definition.

We believe that a clear and inclusive definition is critical to the successful implementation of this rule. The crafting of the definition will help determine which conditions and therefore which patients will be eligible to participate in this very important program. We urge you to ensure that the final definition is inclusive enough that individuals with medically intractable epilepsy and/or status epilepticus are included under the FDA definition of a condition that is immediately life threatening.

Epilepsy is a chronic disorder of the brain which is characterized by the tendency to have recurrent seizures. Nearly 3 million Americans are affected with some form of epilepsy. Over 30 percent of epilepsy patients do not attain an

adequate level of seizure control despite appropriate care by general neurologists or epileptologists. These seizures disorders are characterized as “intractable.” We strongly urge the FDA to consider intractable epilepsy as a serious condition.

In the proposed rule the expanded access program is characterized as a program intended for a disease or condition that has no comparable or satisfactory alternative therapy. Individuals with intractable epilepsy are non-responsive to current available medication. These individuals are plagued with seizures that cannot be controlled and occur frequently throughout the day. With no available treatment they have no relief from a condition that seriously impairs their ability to lead productive lives and significantly increases their risk for significant injury or premature death. The constant battle that is imposed on these individuals’ lives by their condition clearly qualifies intractable epilepsy as a serious disease or condition.

In addition there are some forms of epilepsy that would qualify as immediately life threatening. A form of epilepsy known as status epilepticus which is characterized by continuous or repeated seizures may carry mortality rates up to 6%. This level of risk of death defines status epilepticus as an immediately life threatening condition.

With approximately 1% of the population in the United States diagnosed with epilepsy it is a fairly common condition. Most – nearly two thirds – respond favorably to medication. Yet, for too many there is no available medication and the disease has a significant debilitating impact on their life and for a subset of these individuals the condition can be life threatening.

NAEC urges the FDA to ensure that the final definition of serious and life threatening that is implemented is broad enough to include both intractable epilepsy and status epilepticus.

NAEC appreciates the opportunity to provide input in this very important process. Please contact Ellen Riker at ellen@marcassoc.com or 202-833-0007 for further information or questions.

Sincerely,



Robert J. Gummit, MD
President



David M. Labiner, MD
Board Member