February 23, 2007

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 50852

RE: Docket No. 2007N-0005

To Whom It May Concern:

On behalf of the Alliance for Drug Safety and Access (ADSA), we appreciate the opportunity to offer comments from a patient's perspective on the reauthorization of the Prescription Drug User Fee Act (PDUFA) and provide recommendations in response to the Federal Register of the Food and Drug Administration (FDA) published on January 16, 2007. We thank you for taking this important step to ensuring that patients have speedy access to safe and effective medicines and we look forward to continuing to work with the FDA on this important issue.

ADSA represents over 30 million patients, including those suffering from HIV/AIDS, Parkinson's disease, spinal cord injuries, paralysis, multiple sclerosis, leukodystrophies, Tourette Syndrome, and over 6,000 known rare diseases, and over 100,000 providers of care to pediatric patients and individuals with mental illness. One of our primary mandates is to ensure that patients do not have to choose between speed and safety when it comes to their health and we believe that if empowered properly, FDA could ensure that treatments are available to patients as quickly as possible, while still maintaining quality safety standards.

While ADSA is encouraged to see that user fees in PDUFA IV proposals include funds specifically designated for drug safety activities, we take a similar position as the Institute of Medicine (IOM) that more resources, as well as performance goals, must be dedicated to drug safety in order to address the issue appropriately. Increased resources, including those required to effectively collect and analyze post-market safety data, must be matched by increased authority for FDA to assess safety issues and increased enforcement tools to ensure patient safety.

To shift the current drug safety paradigm from its existing structure to one that adopts more of a life-cycle approach to safety issues, as IOM recommends, significant resources will be required to raise the level of these activities at FDA, particularly in the Office of Epidemiology and Surveillance (OSE), formerly the Office of Drug Safety (ODS). In particular, ADSA recommends that the following items be considered among the highest priority, where significant authority and resources are most needed:

- Post-market studies – FDA needs authority and resources to require post-market studies, including cohort studies and studies of significant off-label uses. Resources for staff to design, review, and provide guidance for these studies is necessary to ensuring that safety issues are addressed in a timely way. Studies of off-label uses are essential in ensuring that safety information is analyzed for drugs patients' use in the real world. Given that one-fifth of prescriptions written in 2001 were for off-label uses, it is critically important to extend FDA authority to require studies for off-label uses.

- Staff coordination – The Office of Surveillance and Epidemiology (OSE) needs to be resourced to participate effectively in new drug review, so that OSE staff can be included on new drug review teams without adversely impacting new drug review time. Communication and cooperation between OSE and the Office of New Drugs (OND) is of paramount importance and should be fostered by structured interaction between these offices at every juncture of drug development, including post-marketing phases.

- Label changes – FDA needs authority and resources to mandate label changes to reflect new safety information, especially if dangerous side effects are discovered. Data shows that safety-related changes remain high for long periods of time, often eight years after a product has been approved. Therefore, granting greater authority to FDA to determine these label changes is critical.

- Clinical trials registry and results databases – Authority and resources are needed to create a mandatory, publicly accessible, user-friendly database of clinical trials and their results. Because valuable safety information is often revealed during Phase II trials, we endorse the IOM recommendation for their inclusion. The database must also include medical device products, so that it serves as one seamless source for patients, as a previous IOM report on post-market safety of pediatric medical devices cited in July 2005. In addition, ADSA recommends the database be retroactive to include earlier trials, which best serve patients' needs.

- Flexible enforcement tools – FDA needs authority to ensure compliance with these new safety protections through adequate civil monetary penalties that are both meaningful and effective, including civil monetary penalties regarding the clinical trials registry and results databases.

- Direct-to-consumer advertising – FDA needs authority to review direct-to-consumer advertisements of all different mediums, including print, radio, and television.

In addition, ADSA recommends that several administrative changes be pursued including:

- Transparency – Within the context of a life-cycle approach to drug safety, ADSA recommends that the development of risk-benefit plans and dispute resolution processes include patient and provider input. Patients offer a critical voice in drug safety decisions that affect their health.

We greatly appreciate the opportunity to comment on this critical issue to patients and look forward to continuing to work with FDA to ensure patient safety. Enclosed please find a brief fact sheet with information about the coalition and our members. If you have any questions, or would like any additional information, please contact Jen Pollakusky from the Elizabeth Glaser Pediatric AIDS Foundation at 202-296-9165 or Diane Dorman from the National Organization for Rare Disorders (NORD) at 202-496-1296.

Sincerely,

Alliance for Drug Safety and Access (ADSA)