NATIONAL CONSUMERS LEAGUE
1701 K Street, NW, Suite 1200, Washington, DC 20006
PHONE (202) 835-3323 FAX (202) 835-0747 www.nclnet.org

February 23, 2007

Re: Prescription Drug User Fee Act; DOCKET NO. 2007N-0005

On behalf of the National Consumers League (NCL), we would like to thank you for the opportunity to comment on the possible fourth extension of the prescription drug user fee act (PDUFA). As expressed in earlier comments, NCL believes that the work of the Food and Drug Administration (FDA) is of such critical public health importance that it warrants continuous and adequate funding from the general Treasury. With current appropriations, however, the user fee system appears to be necessary for the foreseeable future. In fact, given the shape of the Federal budget, our society's increasing reliance on FDA regulated products, and the need for expanded FDA activity in the area of product safety, we concur with the proposed increase in the level of user fees. Ideally, the user fee funds would be applied to the general FDA budget – with no conditions for its use. While Congress has, to date, allowed the regulated industries to dictate how FDA allocates its resources, we believe that this is a highly flawed system and support legislative efforts to de-couple fees from specific activities.

Established in 1899, NCL is the nation's oldest nonprofit consumer education and advocacy organization. NCL provides government, businesses, and other organizations with the consumer's perspective on numerous policy issues including child labor, privacy, food safety, and medication safety and information. From the first Pure Food and Drug laws passed in 1906 to the more recent FDA Modernization Act, NCL has been working – often alongside the Agency - to ensure that the public's well being is adequately represented and protected.

It is in this context that NCL acknowledges the Agency's recently proposed efforts to expand funding for critical – and woefully under-funded – infrastructure and capacity building activities, but questions some of the proposed means by which this would be achieved. For example, NCL strongly supports the recommendation to revise the inflation and workload adjusters, but questions the wisdom of using new pre-market review resources to develop review plans with agency "deliverable" dates for feedback to sponsor companies, which essentially creates another sponsor-oriented step in the pre-market review process.

We will direct our remaining comments as follows.

The Proposed Budget

NCL is generally pleased that the final FY 2007 congressional appropriations for the agency, as well as the President's 2008 budget request, provide substantial increases. We hope that this increase will represent only the beginning of a substantial investment in a crucial government function that has long been subject to severe resource erosion.

We hope, in particular, that additional resources can be directed to product safety and technology infrastructure. While the tentative PDUFA agreement calls for an increase in safety-related spending of $29 million, it is still woefully inadequate relative to what is needed – and to what was formally recommended by the recent Institute of Medicine report.

NCL is also deeply troubled by the state of information technology within the agency, and would encourage far greater appropriations and fees for more timely modernization. The FDA estimates that it needs an investment of roughly $20 million annually, for 5 years, just to bring its systems into the 21st century. This is far more than the $4 million currently provided in this PDUFA agreement. We also would like to see specific timelines for implementation of electronic applications filing, petitions, adverse event reports and other agency communications.

The Postmarket Safety System

We are pleased by the additional (albeit insufficient) allocation of resources for postmarket safety, and particularly applaud the agency for proposing an eligible safety review period of more than 3 years. We hope that removing the restriction of applying user fee resources to safety review beyond 3 years will help detect product safety issues throughout the course of their use, and not just immediately post approval.

One of the proposed postmarket safety initiatives involves awarding an FDA contract to an external research organization for the purpose of "modernizing the process of pharmacovigilance." Studies under this contract would evaluate the different methods of adverse event collection – presumably ongoing in the US only – and their implications for patient safety. Given the dearth of adverse event information reported into the MedWatch system, and the lack of "gold standard" reporting and collection tools used in this country, we would advise that the contract research team be instructed to look beyond those adverse event systems that exist in the US. If only the current set of rudimentary options are considered, then even the best of those approaches may not yield any meaningful results in terms of patient safety. A broader scan of "best practices" in the US and abroad likely would prove more instructive, and ultimately better for the safety of US consumers.

The Proposed Recommendation for the Review of Direct-to-Consumer Advertising

NCL has long been interested in ensuring that consumers receive accurate and useful information about their healthcare, including information about the safe and effective use of prescription drugs. If DTC is to remain an integral part of this communications process, then we agree that product sponsors should be assessed a fee as part of their submission of any DTC add – regardless of medium - to the Agency. We believe that the revenue derived from the new fee could be used to support a number of currently under-funded Agency activities, including but not limited to:

1. Conduct of post market safety studies, as deemed necessary on a case by case basis,
2. Expanded use of large databases to detect safety issues not identified in the pre-market clinical trial setting,
3. Expanded use of secondary data to conduct relative safety and effectiveness analyses,
4. Increased expenditure on public information sharing – about emerging safety issues as well as disease awareness, and
5. Hiring of additional staff to review - and respond to industry feedback in a timely fashion – on all DTC adds pre deployment.

The PDUFA IV proposed recommendation for DTC review falls short on three major fronts: First, as proposed, user fees would only be assessed for the review of television advertisements – not the full spectrum of media reaching US consumers. This is highly problematic given the extent to which campaigns tend to be coordinated and integrated across multiple media in order to maximize impact. Second, it appears as though the PDUFA fees proposed in this recommendation would not be applied to any of the recommended activities mentioned above, save for hiring of additional review staff. Third, and most importantly, this

proposal fails to address the fact that product sponsors have no incentive (nor stick) compelling them to submit their adds for agency review. Absent authority to make review a condition of broadcasting, we anticipate that the DTC user fee program will go unused and/or unheeded by many sponsor companies. This will leave patients and their health care providers vulnerable to sometimes misleading and deceptive advertising practices.

We believe that the FDA should be granted the authority to require that all DTC ads undergo agency review, and we also support agency authority to place a moratorium on all DTC advertising for new drugs deemed to have inadequate safety information. Based on available safety data, the Agency could be given latitude in determining the appropriate length of the moratorium on a product by product basis. NCL also would support adding a third "provisional" status for some new drugs. Such a status would allow for limited exposure of the product to appropriate patients, thereby mitigating the likelihood of inappropriate use and over exposure while additional post-approval safety data collection is ongoing.

Finally, while we appreciate the agency's recent efforts to educate and engage consumer and patient organizations through briefings and discussion forums, we hope that the FDA will support Congressional language requiring greater consumer and patient input in the PDUFA V re-authorization process. Thank you for your consideration of these comments and recommendations.

Sincerely,

LINDA F. GOLODNER
President