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Statement of Sally Greenberg, Executive Director
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Over-the-Counter (OTC) Monograph User Fees: Public Meeting
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The National Consumers League (NCL) commends FDA for holding this public meeting to gather stakeholder feedback on proposed OTC Monograph User Fees. My name is Sally Greenberg, Executive Director of NCL. Founded in 1899, the National Consumers League has long been concerned with ensuring the safety of foods and drugs. Among NCL's top priorities are ensuring the safety, effectiveness, and appropriate use of both prescription and over-the-counter (OTC) drugs, and medication adherence, which we've helped advance through our *Script Your Future* Campaign.

The FDA's *Federal Register* notice states that in the OTC market, there are approximately 800 active ingredients for more than 1,400 different therapeutic uses. In addition, about $32 billion in OTC medicines were sold in the US last year, according to the Consumer Healthcare Products Association, up 4.5 percent from 2010. For the more than 240 million Americans who use OTC medicines every year, these drugs undoubtedly play a vital role in keeping consumers healthy and helping them to feel better when they're sick.

However, it appears that with the burgeoning OTC marketplace, the FDA is seriously under-resourced, with only 18 full-time employees (FTEs) assigned to oversee the entire OTC market. This is the same number of FTEs it takes to review one novel prescription drug application.

While the FDA has made determinations about the safety and efficacy of the active ingredients in thousands of products through the OTC monograph review process, there are still many pending monographs for which the ingredients have not been determined to be GRASE – generally recognized as safe and effective for their intended uses.

FDA estimates that at the current funding level, it would take decades to review and finalize the spectrum of OTC drug monographs that are currently in non-final status. The agency is asking for additional resources to finalize pending OTC monographs and

address safety issues faster and more efficiently. Finalizing FDA review of these ingredients, as well as devoting additional resources to expeditiously modify labels for new safety concerns, would better serve the public. In addition, a user fee program could benefit both consumers and industry by allowing for more timely review of innovations and new ingredients, ultimately leading to the availability of new and improved OTC options. For these reasons, NCL agrees that it makes sense to create a pathway for the FDA to have additional resources to manage this growing number of OTC products.

With regard to the implementation of OTC user fees, NCL recognizes that the ingredient-based OTC monograph review process may not lend itself to user fee assessment. FDA should consider implementing set user fees such as product and establishment fees that would generate a steady, predictable source of funds for the agency.

That said, we do have a few concerns if the agency moves forward with this proposal. First, we would like to ensure that the FDA take care not to impose burdensome fees on newer or smaller innovative firms that may find it difficult to absorb the fees. Perhaps a tiered fee system should be contemplated for such companies. Secondly, we are mindful of the concerns expressed by some that because industry pays the user fees, industry thereby controls the agency's agenda and process. We urge the FDA to make it abundantly clear that it will act independent of industry influence and always work to advance the public's access to safe and effective OTC products.

As for performance goals as part of an OTC user fee program, NCL would like to see FDA commit to initiating a certain number of OTC monograph finalizations per year and recommend the publication of an annual report on progress in addressing the OTC monograph backlog, including highlighting the approval of new and innovative treatments.

We commend the FDA for soliciting the views of the many stakeholders who will be affected by this program and particularly appreciate giving consumer organizations the opportunity to share our views. We look forward to working with the FDA and with the OTC industry, as appropriate, to design a balanced and fair user fee program for OTC drugs.