HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

November 16, 2016

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2012-N-0882 Comments of Healthcare Supply Chain Association on "Generic Drug User Fees; Public Meeting"

The Healthcare Supply Chain Association (HSCA) appreciates the opportunity to provide comment on the U.S. Food and Drug Administration's (FDA) proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments (GDUFA) of 2012.

HSCA's member group purchasing organizations (GPOs) are critical partners to virtually all of America's 7,700+ hospitals, as well as the majority of its 68,000+ non-acute care providers, including nursing homes, clinics, and surgery centers. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. We are also committed to helping hospitals and other healthcare providers deliver effective and affordable care to the patients they serve.

Patients have long relied on generic drugs to increase access to and reduce the costs of essential medications. For years, robust competition in the generic drug market has successfully driven down costs. However, generic price spikes, often caused by monopoly or duopoly situations, are now jeopardizing access to care for millions of Americans. HSCA and its members are concerned that long product review and approval times for Abbreviated New Drug Applications (ANDAs) could be stifling the ability of manufacturers to introduce competition in the market to help mitigate price spikes.

We applaud the FDA for its ongoing efforts to increase the overall rate of drug review and approval, facilitate greater access to generic drug products, and improve the efficiency and effectiveness of the review process. We urge the FDA to strive for approval of ANDAs in the first cycle and to commit to issuing product-specific guidance on 90 percent of products two years before the first lawful potential approval date.

As you know, GDUFA I underestimated the volume of ANDAs the FDA would receive per year and the resources needed to handle the influx of ANDAs in a timely manner. We urge FDA to ensure that it adopts efficient human resource processes that provide appropriate staff and resources necessary to

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continue to meet its safety mandate while also providing for an expeditious approval process for new drugs.

HSCA and its member GPOs consistently advocate for policy solutions that reduce costs, increase competition, and remove barriers to market entry. We think FDA's recommendations for GDUFA reauthorization are an important step. We also support bipartisan legislation from Senators Collins (R-ME) and McCaskill (D-MO), the "Increasing Competition in Pharmaceuticals Act" (S. 2615), that would mandate FDA priority review of ANDAs for products with only one manufacturer. We have urged Congress to consider mandating priority review for generic injectable drugs with two or fewer manufacturers. Generic injectables are the workhorses of acute care facilities and bring great value to health care providers and patients.

Finally, we have encouraged Congress to mandate priority review of an ANDA in instances where there have already been significant spikes — specifically, where the market price of an existing product increases at a rate of more than five times the percent change that occurred in the Prescription Drugs Index of the Consumer Price Index for the previous year.

HSCA and its members look forward to continuing to work with the FDA as the agency finalizes its reauthorization of GDUFA. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or tebert@supplychainassociation.org.

Sincerely,

Todd Ebert, R.Ph.
President and CEO