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HSCA URGES FDA TO ENSURE PROPER IMPLEMENTATION OF GENERIC DRUG LEGISLATION AND TO ADDRESS GROWING BACKLOG OF NEW DRUG APPLICATIONS

HSCA Offers Policy Recommendations to Speed the Approval of Abbreviated New Drug Applications (ANDAs) and Increase Competition in the Generic Drug Marketplace

Washington, DC (June 3, 2015) – The Healthcare Supply Chain Association (HSCA) recently [sent a letter](#) to the U.S. Food and Drug Administration (FDA) urging timely implementation of the remaining provisions of the Generic Drug User Fee Amendment (GDUFA). HSCA notes in the letter that GDUFA is vital to the safety, efficacy and affordability of the generic drug market, the healthcare supply chain and patients, and calls on the agency to improve the approval process for the growing backlog of Abbreviated New Drug Applications (ANDAs) to increase competition in the marketplace.

“While we appreciate the work FDA has completed on GDUFA, the growing backlog of new drug applications is creating barriers to affordable and effective treatments for patients and hospitals,” said HSCA President Curtis Rooney. “We want to ensure the primary objectives of GDUFA—improved access, transparency and safety—are accomplished in a timely manner so that generic drugs can continue delivering savings across the entire healthcare supply chain.”

In its letter, HSCA outlined the following recommendations to FDA to help safely expedite approvals and increase agency transparency:

- FDA should issue **Target Action Dates (TADs)** for **all backlog ANDAs**;
- FDA should **post the number of all ANDAs** submitted as well as **current backlog numbers** on its website;
- FDA should **fast-track potential generic drugs into markets** where high drug prices result from manufacturers taking unfair advantage of **shortages or market domination**.

To read the full letter, click [here](#).

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About the Healthcare Supply Chain Association (HSCA)

The Healthcare Supply Chain Association, formerly the Health Industry Group Purchasing Association, is a broad-based trade association that represents 14 group purchasing organizations, including for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and healthcare provider alliances. HSCA’s mission is to advocate on behalf of healthcare group purchasing associations, to provide educational opportunities designed to improve efficiencies in the purchase, sale and utilization

of all goods and services within the health industry and to promote meaningful dialogue between GPOs. For more information, visit www.supplychainassociation.org. Follow HSCA on Twitter [@HSCA](https://twitter.com/HSCA).