HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

May 21, 2015

Dr. Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Re: Generic Drug User Fee Act Implementation to Date

Dear Dr. Ostroff:

The Generic Drug User Fee Amendment (GDUFA) is vital to the safety, efficacy and affordability of the generic drug market, the healthcare supply chain, and patients. In the GDUFA agreement U.S. Food and Drug Administration (FDA) and drugmakers reached in 2012, the primary objective was to strengthen the generic drug market through the following measures:

1. Increase patient access to generic treatments by facilitating more punctual drug reviews in a more predictable manner;
2. Improve transparency between the generic manufacturers and FDA; and
3. Ensure FDA has the resources necessary to oversee the global drug supply by holding all stakeholders to the same one quality standard.

GDUFA is now halfway through its five year implementation period. While we appreciate the work FDA has completed thus far in building the necessary frameworks for it we believe some of these initiatives have inadvertently diminished the mission of the FDA Office of Generic Drugs (OGD) to achieve new generic approvals as quickly and safely as possible. We write you to ensure the primary objectives of GDUFA—improved access, transparency and safety/quality—are accomplished in a timely manner to combat a growing backlog of Abbreviated New Drug Applications (ANDAs) and help address the increase in submissions. To this end we offer to suggestions that we believe will assist the process.

Status Check on Access/Approvals and Transparency

According to a private sector survey, since GDUFA was negotiated in FY2011 the OGD's median review time for product approval has continually risen. Before GDUFA, review time was 30 months. By FY2012 it was 31 months; FY2013 it was 36 months; and FY2014 projections estimate a median time of 42 months.[1] Furthermore, the sum of both tentative and final approvals has fallen. In 2012 there were 612 overall approvals, 2013 had 535 approvals, and 2014 had only 500.

These delays not only affect the manufacturers, providers and other stakeholders, but directly affect patients as well. Additionally, we are concerned that the lack of ability to precisely account for overall manufacturer scheduling could result in drug shortages or a decreased availability of generic drug supplies. Fewer generic drugs in the market affect planning, costs and safety across the entire healthcare supply chain.

[1] FDA has not yet made the 2014 median approval times publicly available. The median approval time across more than one hundred twenty various industry approvals for which information is available is forty-two months.

2025 M Street NW ■ Suite 800 ■ Washington, DC 20036
p: (202) 367-1162 ■ *f:* (202) 367-2162 ■ *e:* info@supplychainassociation.org ■ www.supplychainassociation.org

The response from OGD to the generic drug industry's concerns over the decrease in approvals is encouraging, but should be more robustly executed. OGD indicated in February 2014 that it would start allocating target action dates (TAD) to any application submitted before October 1, 2014. This initiative provides more a transparent and predictable pathway to market, and we urge FDA to issue TADs for all backlog ANDAs. To aid in this process we suggest that FDA publicly post the number of all ANDAs submitted and the backlog on its website.

We also suggest that the FDA OGD fast-track potential generic drugs into markets where high drug prices result from manufacturers exploiting shortages and monopolies. The FDA could focus on generic drugs in shortage or that have a price increase that exceeds the Producer Price Index (PPI) or Consumer Price Index (CPI-U).

Influence and Effects on the Generic Drug Market and Supply

The U.S. healthcare system has lost billions in estimated savings from generic approval delays which, according to private sector industry surveys, are facing 50-month approval times for first-time generic applications. If the cost savings expected by Hatch-Waxman are to be realized, the approval of generic applications must be more swiftly enacted on the earliest legally eligible date.

The impact of these delays are felt all across the healthcare industry; providers, suppliers, manufacturers and patients each face limited access to alternatives for expensive brand products when fewer generics are in the market. The American healthcare system is strained as higher prices are unnecessarily forced onto payers and patients due to the lack of competition caused by approval delays.

Delays also cause other market disruptions in the generic business. As FDA knows, lawmakers in Washington are actively looking into root causes for recent generic drug price spikes. Increased generic competition and swift product approvals are critical cost-saving agents and would ultimately help placate this market.

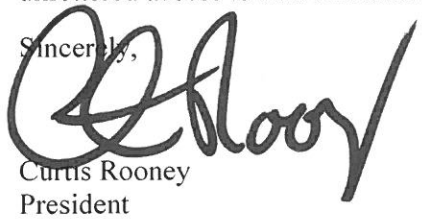
The Path Ahead

FDA and OGD have an excellent track record in approving generic drugs and applying the provisions of the Hatch-Waxman Act to the American healthcare system. The Agency's dedication to accurately representing the mission of the Hatch-Waxman Act is one of the primary reasons the United States is a global leader in generic drugs. Additionally, we applaud the FDA's recent plan outlined in December to increase communication for active ANDAs and work to significantly increase the approvals of backlogged ANDAs.

GDUFA renewal is dependent on proven results; the approval delays in the past three years have put the generic industry, and by extension the healthcare system, into many complex situations. By expediting more approvals and creating greater transparency, the market for generic drugs can continue to positively impact all aspects of healthcare.

As you move forward, we are ready to work with you to ensure patients and healthcare professionals have unfettered access to safe and affordable generic drugs during GDUFA implementation.

Sincerely,



Curtis Rooney
President

CC: Janet Woodcock, MD, Director, Center for Drug Evaluation and Research
Kathleen Uhl, MD, Director, Office of Generic Drugs
The Honorable Lamar Alexander (R-TN)
The Honorable Patti Murray (D-WA)
The Honorable Fred Upton (R-MI)
The Honorable Frank Pallone (D-NJ)