Via Electronic Submission to: www.regulations.gov

August 20, 2020

Tiana Barnes  
Food and Drug Administration  
Center for Drug Evaluation and Research  
10903 New Hampshire Ave., Bldg. 51, Rm. 6196  
Silver Spring, MD 20993

Re: Generic Drug User Fee Amendments; Public Meeting; Request for Comments (Docket No. FDA–2020–N–1459)

Dear Ms. Barnes:

The American Pharmacists Association (APhA) appreciates the opportunity to provide our perspective on the implementation of the Generic Drug User Fee Amendments of 2017 (GDUFA II) to date and to offer some considerations as work begins on GDUFA III. Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA believes that the Food and Drug Administration (FDA) has made good progress on GDUFA II’s goals. The agency has improved the efficiency of the generic drug review and approval process and increased consumer access to high-quality, safe and effective, and affordable generic drugs. The availability of affordable, quality generic drugs is critical to patient health and results in significant cost savings. According to the Association for Accessible Medicines (AAM), in 2018, generic drugs accounted for 90% of prescriptions in the United States, but only 22% of the costs. In 2018 alone, generic drugs saved the U.S. health care system $293 billion, and $2 trillion over the past 10 years. In order to continue to reap the benefits of generic drugs, FDA must build upon the successes of GDUFA II.

As FDA begins to consider GDUFA III, we urge the Agency to include the following areas in the Commitment letter:

**Continue to Improve Review Efficiency and First Review Cycle Approvals**

APhA is pleased to see that FDA has met or exceeded the 90% performance level for the GDUFA II review goals. Under GDUFA II, FDA committed to review and act on 90% of a number of submission types, including the following:

- FDA agreed to review and act on standard original ANDAs within 10 months of the date of ANDA submission. As of September 30, 2019, FDA has met 97% of the FY 2019 goal for these applications.

- FDA agreed to review and act on priority original ANDA submissions with an 8 month goal date. As of September 30, 2019, FDA met 100% of the FY 2019 goal for these applications.

- FDA agreed to review and act on standard prior approval supplements (PASs) (if pre-approval inspection is not required) with a 6 month goal date, and met 98% of that goal.\(^2\)

However, there is room for improvement in first review cycle approvals. A 2019 GAO report found that FDA only approved 12% of generic drug applications in the first review cycle in FYs 2015-2017.\(^3\) On average, applications went through 3 review cycles before approval, delaying the generic drug’s arrival to market.\(^4\) Improving first cycle approvals should continue to be an area of focus for GDUFA III.

**Continue to Improve Predictability of FDA Funding, Resource Management Planning, and Hiring and Retention of Highly Qualified Staff**

For FY 2019, FDA had net collections of $497 million in generic drug user fees, spent $465 million for the generic drug review process, and carried a cumulative balance of $204 million forward for future fiscal years.\(^5\) In GDUFA III, it will be critical for FDA to continue to be a good steward of its financial resources. APhA is encouraged by FDA’s resource management planning and modernized time reporting implementation to date. Moving forward, we urge FDA to fully enable its resource management planning capabilities and to adopt its proposed capacity planning adjustment (CPA) methodology to better assess the sustained workload and GDUFA

---


\(^4\) Id.

resource needs.\textsuperscript{6} In addition, FDA must continue its efforts to hire and retain highly qualified scientific and regulatory staff.

**Improve Drug Safety**

The recent recalls of generic angiotensin II receptor blockers (ARBs) due to nitrosamine contamination\textsuperscript{7} have highlighted the importance of ensuring drug safety. To protect patient health, APhA urges FDA to include continuous quality improvement measures and safety oversight in GDUFA III. A larger proportion of generic drug user fees should be directed to postmarket surveillance. Performing active, diligent postmarketing pharmacovigilance is critical for proactively identifying possible areas of concern for medications and ensuring the ongoing safety of medications post-approval. In addition to safety surveillance, FDA should direct more resources towards hiring and training investigators. To the extent possible, foreign inspections should be unannounced. In addition, FDA should put in place better data systems for tracking the source of drugs when problems arise.

**Address Drug Shortages and Strengthen the Pharmaceutical Supply Chain**

APhA appreciates FDA’s and the CDER Drug Shortage Staff’s efforts to address our nation’s drug shortage problem, including early notification requirements, expedited inspections and reviews of manufacturing sites, the establishment of an Agency Drug Shortages Task Force and stakeholder listening sessions, and the publication of FDA’s October 2019 report examining the root causes of drug shortages and potential solutions.\textsuperscript{8}

Despite these advances, drug shortages continue to occur, especially in the context of COVID-19, where we have seen shortages of critical drugs used to treat COVID-19 patients. APhA appreciates that FDA has prioritized assessment of generic drug therapies for COVID-19, especially drugs used in the hospital setting. We urge FDA to continue to focus on alleviating drug shortages and strengthening the pharmaceutical supply chain as part of the GDUFA III reauthorization. APhA calls for widespread development of redundancy and risk mitigation strategies by manufacturers of inactive and active ingredients on a facility and product basis to ensure reliable and consistent availability of safe and high-quality drugs. APhA also urges greater transparency, accuracy, and timeliness of information and notification to health care professionals regarding drug shortages and anticipated shortages, product quality and manufacturing issues, supply disruption, and recalls.

APhA recognizes the monumental task that FDA has in implementing the Drug Supply Chain Security Act (DSCSA), which impacts many generic drug products. We recommend that GDUFA III include funding to provide FDA with resources to appropriately and adequately


develop standards, processes, and data systems to implement the DSCSA by the 2023 statutory deadline and support the maintenance, enforcement, and surveillance for compliance with the requirements.

Enhance the Development and Review of Complex Generic Drug Products

Through its pre-ANDA program, FDA has made great strides in enhancing the development and review of complex generic drug products. By utilizing earlier and more frequent meetings between FDA and the applicant, FDA has facilitated the development of more complete submissions and a more efficient ANDA review process. During FY 2019, FDA facilitated 76 pre-ANDA meetings for prospective applicants, published 141 product-specific guidances for complex products, and addressed 1,232 controlled correspondence for complex products.9 As part of GDUFA III, APhA urges FDA to continue its efforts to maximize scientific and regulatory clarity with respect to complex generic drug products. APhA also recommends that a portion of GDUFA III resources be devoted to supporting FDA’s scientific research agenda.

Foster Competition and Lower Drug Prices

While drug pricing is outside the purview of FDA, APhA welcomes any steps FDA can take in GDUFA III that will promote competition and lead to lower drug prices. For example, APhA supports the competitive generic therapy (CGT) pathway established by the FDA Reauthorization Act (FDARA) for drugs with “inadequate generic competition.”10 At the request of the applicant, FDA may expedite the development and review of an ANDA for a drug designated as a CGT.

In addition to the CGT pathway, APhA appreciates the establishment of FDA’s webpage on the CREATES Act implementation and how generic drug applicants can request a Covered Product Authorization (CPA) from FDA for reference listed drugs (RLDs) subject to a Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use (ETASU).11

Finally, APhA recommends that GDUFA III include funding to educate patients and health care providers, including pharmacists, on the benefits of generic drugs in order to further increase their uptake.

Conclusion

APhA appreciates the opportunity to provide our initial thoughts on GDUFA III. We look forward to continuing to work with FDA, manufacturers, and other stakeholders as the reauthorization process continues. If you have any questions or need additional information, please contact me at kbolte@aphanet.org or (301) 648-0673.

10 Food and Drug Administration Reauthorization Act of 2017 (FDARA), P.L. 115-52.
Sincerely,

Karin L. Bolte, JD
Director, Health Policy