Summary of views and comments received regarding proposed recommendations for GDUFA III
Docket No. FDA-2020-N-1459-0017

Executive Summary

The Generic Drug User Fee Amendments (GDUFA) authorize the Food and Drug Administration (FDA or Agency) to assess and collect user fees for human generic drug activities. The current authorization of GDUFA expires on September 30, 2022. To develop recommendations for the third authorization of GDUFA (GDUFA III), FDA has followed the process described by statute, including two public meetings with associated dockets for public comment, monthly consultation meetings with patient and consumer advocates, and negotiations with the regulated industry.

The statute further requires FDA to publish the recommendations in the *Federal Register* and hold a public meeting at which the public may present its views. This public meeting was held on November 16, 2021. FDA must then consider the public views and comments and revise such recommendations as necessary. When transmitting the recommendations to Congress, the Secretary must provide a summary of the public views and comments and any changes made to the recommendations in response to the views and comments. This document fulfills that requirement.

The process used to develop the recommendations for the reauthorization included significant opportunity for patient and consumer advocates, and other stakeholders to provide their views and priorities. FDA considers this input important to the shaping of the proposed recommendations for program enhancements.

Overall, the public docket comments received on the proposed set of recommendations reflect general support for the recommendations for reauthorization. The most cited areas of support were for FDA's commitments to further promote drug development of complex products and reducing review cycles.

A few comments expressed concerns about the need for more direct participation in the negotiations with industry and the implementation of the commitments to ensure safety and efficacy of generic drugs.

Overall, given the general support expressed for the recommendations for the reauthorization of GDUFA at the public meeting and in the comments received in the public docket, FDA has not made changes to the recommendations.

Introduction and Background

GDUFA authorizes FDA to assess and collect user fees for human generic drug activities. The current reauthorization of GDUFA (GDUFA II) was part of the Food and Drug Administration Reauthorization Act of 2017 (FDARA). This authority expires on September 30, 2022. FDA began the reauthorization process, in preparation for GDUFA III, with a public meeting held on July 21, 2020. Following the meeting, a docket was open for 30 days for the public to submit written comments. In September 2020, FDA began concurrent negotiations with industry and monthly discussions with patient and consumer advocates to develop the proposed

recommendations for the next GDUFA program. The groups who participated in the monthly discussions included patient advocacy groups, consumer advocacy groups, healthcare professional groups, public policy advocacy groups, and scientific and academic experts. These discussions concluded at the end of August 2021. Minutes of these meetings are posted on FDA's website at https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-reauthorization-stakeholder-meetings, and minutes of the negotiations between FDA and industry are posted on FDA's website at https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-reauthorization-negotiation-sessions.

The development of the GDUFA III proposal complies with the following requirements under section 744C(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act):

> *(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—*
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> *(A) present the recommendations developed under paragraph (1) [section 744C(f)(1)] to the Congressional committees specified in such paragraph;*
> *(B) publish such recommendations in the Federal Register;*
> *(C) provide for a period of 30 days for the public to provide written comments on such recommendations;*
> *(D) hold a meeting at which the public may present its views on such recommendations; and*
> *(E) after consideration of such public views and comments, revise such recommendations as necessary.*
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> *(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2022, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.*

FDA has followed the process described in section 744C(f)(4) of the FD&C Act and the Agency is publishing this summary in preparation for the transmittal of recommendations to Congress pursuant to section 744C(f)(5) of the FD&C Act.

Following administration review and clearance, FDA posted the package of proposed recommendations at https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii and published a *Federal Register* notice summarizing the proposed recommendations on October 29, 2021. FDA also met on October 27, 2021, with the bipartisan committee staff from the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions to present the proposed recommendations, in addition to meetings with health staff from these Senate and House committees on December 10 and 17, respectively. FDA held a public meeting on November 16, 2021, to take public comment on the proposed package; a transcript and recording of that meeting can be found on FDA's website at this link: https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-11162021-11162021. The public docket for that meeting subsequently closed on December 12, 2021. The written comments submitted to the docket can

be found on FDA's website at this link: https://www.regulations.gov/document/FDA-2020-N-1459-0017/comment.

This document provides a summary of the eight written comments submitted to the public docket before the close of the comment period, which included comments from patient groups, consumer advocacy groups, trade groups, and a professional society. An additional comment from a healthcare company was submitted the day after the deadline, so their comments do not appear on the public docket, but FDA is also including them in this summary.

Following its review of the public comments, FDA has determined that no changes to the originally proposed recommendations are necessary, and FDA intends to send the recommendations to Congress in accordance with the procedures in section 744C(f) of the FD&C Act.

Overview of Public Comment

Based on a review of the public input received in the docket, FDA has received widespread support for the GDUFA III recommendations. Several stakeholders expressed support for enhancements to reduce review cycles such as the use of "Imminent Actions." Comments supported enhancements to improve generic drug development of complex products such as the post-Complete Response Letter Scientific Meetings, Enhanced Mid-Cycle Meetings and the addition of Product-Specific Guidance metrics. A trade association expressed support for the continued fee exemption for positron emission tomography drug manufacturers and support for the electronic process for self-identification.

FDA also received comments raising the following concerns:

1. FDA must ensure any changes to the generic drug review and approval process prioritize patients' needs, including availability of complex generics.

   FDA remains committed to prioritizing the assessment of drug product applications for products that can address public health priorities for patients. As described in FDA's Manual of Policies and Procedures (MAPP) 5240.3, *Prioritization of Original ANDAs, Amendments, and Supplements*, the Agency prioritizes abbreviated new drug application (ANDA) assessment for important public health priorities such as drug products that could address drug shortages or public health emergencies, and "first generics," which are the first generic drug products approved to compete with a brand product. In addition, FDARA provides a pathway, the competitive generic therapy designation, to expedite the development and assessment of ANDAs with "inadequate generic competition."

   FDA is proposing a number of enhancements to the program to foster complex generics, a market identified by stakeholders as a priority for further generic competition. The "pre-ANDA" program established under the GDUFA II Commitment Letter provides prospective applicants developing a complex generic product the ability to engage with FDA prior to submission of a generic drug application. This provides valuable exchange

of knowledge between FDA and industry regarding complex generics. The recommendations in GDUFA III provide for additional elements to the pre-ANDA program and continued engagement during ANDA assessment, including enhancements to existing meetings and the addition of new opportunities for applicants of complex generics to obtain regulatory advice.

FDA appreciates the input and will consider these comments as it develops its implementation plans, to the extent they are consistent with reauthorization legislation that is passed into law.

2. FDA's Office of Generic Drugs should establish more consistent and formal processes for patient input in addition to the GDUFA reauthorization process.

   FDA collects patient input at the public meetings as part of the GDUFA reauthorization process. In addition, the generic drug program holds public meetings on regulatory science priorities and other topics that enable the public to provide input. The public also has the opportunity to engage with the generic drug program through the Professional Affairs and Stakeholder Engagement Staff in the Center for Drug Evaluation and Research. FDA appreciates the input and will consider these comments as it develops its implementation plans, to the extent they are consistent with reauthorization legislation that is passed into law.

3. Information on the number and percentage of applications rejected should be provided to give an adequate view of FDA's performance as safety gatekeeper for patients and consumers.

   FDA posts information monthly on the number of applications that are approved and the number that receive complete response letters. FDA also posts statistics on the number of applications that were not received for review (see https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-monthly-performance). In addition, each year the Agency provides a comprehensive report to Congress on the performance of the GDUFA program (see https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports). FDA will continue to maintain that transparency, and no changes are needed to the Commitment Letter to address this comment.

After the docket closed, FDA received the following comments from a private healthcare company:

1. Increase transparency with specific FDA actions to advance production strategies and how these steps affect quality and reliability of generic drugs.

   The FDA has been and will continue to be transparent regarding its efforts to advance new manufacturing approaches, strengthen domestic drug manufacturing and increase the domestic supply of quality medical products for consumers (see https://www.fda.gov/news-events/fda-voices/fdas-advanced-manufacturing-initiatives-

helping-provide-quality-human-drugs-patients). Initiatives include work with international regulators on guidelines for continuous manufacturing of drug substances and drug products and the Agency's Emerging Technology Program to offer pre-submission advice to manufacturers of such technologies. In addition, as reflected in the GDUFA III Commitment Letter, an applicant has the option to submit a controlled correspondence to obtain regulatory advice from FDA after the ANDA is approved. We anticipate that many questions will concern manufacturing.

Several comments submitted were outside the scope of the GDUFA reauthorization discussions. These comments were on activities that either involve specific regulatory policies, encompass broader operations beyond the GDUFA program, or cannot be supported by GDUFA user fees under the statute.

1. Enhancements in the Commitment Letter do not adequately include safeguards regarding the safety and efficacy of generic drugs; fail to include monitoring to ensure that the requirements of equivalency are met.

   The generic drug program is designed to help ensure public access to safe, effective and high-quality generic drugs. The high standards for ANDA approval set forth in the FD&C Act and our implementing regulations ensure that FDA only approves generic products that are as safe and effective as their brand counterparts. In addition, FDA has dedicated teams of experts that conduct post-approval surveillance for generic drugs to help ensure the products we approve continue to meet those high standards. To the extent that the comments are recommending regulatory changes, such changes are beyond the scope of the GDUFA negotiations.

2. Concern regarding how the costs of GDUFA research will eventually be passed on to the public.

   The pricing of generic drugs is beyond the scope of the GDUFA negotiations. However, the GDUFA research program is focused on developing the regulatory science to facilitate the development of new generic drugs, in particular, complex generics. By investing in this research, generic drugs should be available to the public more rapidly, potentially resulting in overall cost savings. For example, as mentioned above, the Commitment Letter proposes new goal dates around the development of Product-Specific Guidances for complex products to facilitate development of complex generics which are directly supported by FDA's regulatory science research. FDA also makes our regulatory research available to public stakeholders through a variety of mechanisms. FDA welcomes the public's input on its research priorities (see https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects).

3. Need more clear and transparent regulatory pathways to broaden access in an efficient and effective manner.

   FDA provides general information to the public regarding the regulatory pathways for ANDA approval (https://www.fda.gov/drugs/buying-using-medicine-safely/generic-

drugs). In addition, industry, stakeholders, and the public play a significant role in the agency's guidance development process. FDA welcomes suggestions for guidance topics, accepts proposed draft guidances for consideration, and considers comment on draft guidances before finalizing for implementation. All FDA guidances are posted and anyone can submit comments on any guidance after they are implemented. FDA continuously assesses any input received to develop or revise guidances, as necessary to continuously provide needed clarity and transparency.

4. Improve transparency and accessibility throughout the GDUFA negotiations such as providing information in multiple formats to meet the needs of diverse populations. This includes multiple languages, website content that can be accessed by a screen reader, the use of plain language, closed-captioning and American Sign Language translation.

   FDA makes every effort to make the information it provides to the public accessible through attention to comprehensibility of the language used, providing translations of certain materials and closed captioning for webinars. Additionally, all web postings are compliant with Section 508 of the Rehabilitation Act of 1973 to assure accessibility to all members of the public. We will continue to work to make our posting accessible to diverse populations.

5. Include continuous quality improvement measures and safety oversight. For example, a larger portion of user fees be directed toward post-market surveillance.

   FDA recognizes the value and importance of post-marketing surveillance for safety oversight. However, while the Commitment Letter outlines performance goals that FDA agrees to achieve, the manner in which user fees ultimately authorized by Congress are allocated among particular fee-supported activities, including post-market surveillance, is beyond the scope of the GDUFA negotiations. FDA will continue to prioritize the safety of generic drugs and will consider these comments as it develops its implementation plans, to the extent they are consistent with reauthorization legislation that is passed into law.

Additional topics raised in the comments that are beyond the scope of the negotiations include funding of the Drug Supply Chain Security Act; funding to continue to educate patients and health care providers on the benefits of generic drugs in order to further increase their uptake; modernization of the unapproved drugs initiative to prevent restriction of market competition, and increased transparency in the drug manufacturing supply chain to prevent drug shortages. FDA recognizes the importance of these issues and appreciates the input and will consider these comments as it develops its implementation plans for these activities.

To read more details on all the comments summarized above, FDA recommends visiting the publicly available docket at https://www.regulations.gov/docket/FDA-2020-N-1459/document.

In summary, the public docket comments received on the proposed GDUFA reauthorization recommendations convey feedback that can be addressed without further modifications to the

GDUFA III proposal. Therefore, FDA has not made changes to the current recommendations for the reauthorization of GDUFA.

Conclusion

The process for the reauthorization of GDUFA has benefited from a number of opportunities for stakeholders to provide input into the recommendations. FDA greatly appreciates the significant and thoughtful input provided by stakeholders at the two public meetings and the monthly stakeholder consultation meetings, in addition to the docket comments described above. This input has helped FDA better understand and incorporate stakeholder perspectives and priorities, and this has ultimately contributed to a stronger set of proposed recommendations. Given the general support for the GDUFA III agreement, and while noting that FDA will take the public input received into consideration in implementing the new GDUFA III commitments, FDA has not made changes to the proposed recommendations for the reauthorization of GDUFA.