February 22, 2021

Sally Choe, Ph.D.
Director of the Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Choe:

The undersigned groups represent patients and consumers who rely now – and will in the future – upon complex medicines that treat a variety of serious and chronic illnesses. Greater availability of generic versions of these medicines would improve accessibility and affordability for those patients who are most likely to already have high medical costs.

We thank the U.S. Food and Drug Administration (FDA) for its ongoing work to expand timely access to low cost, high quality generic drugs. In particular, we appreciate the enormous progress the Agency has made to clear the backlog of abbreviated new drug applications (ANDA) and significantly increase the number of approved generic drugs. The success is apparent, with generic drugs accounting for nearly 90 percent of all U.S. prescription by volume[1] and saving the U.S. health care system an estimated $2.2 trillion in the last decade (2010-2019).[2]

Looking ahead towards the Generic Drug User Fee Agreements (GDUFA III), we urge FDA to commit to twin goals: increased efficiency of generic reviews and greater attention to the next generation of generic drugs – complex generics – that, by their nature, require a more intensive review. Appropriated and user fee funding needs to be sufficient to do both.

Likewise, we urge the Agency to consider process improvements to help alleviate uncertainty in the regulatory review process, particularly for complex generics. Only 12 percent[3] of generic products are approved on their first review cycle. Uncertainty in the regulatory review process contributes to review times that range up to four to six years, significantly delaying patient access to lower-cost alternatives. All too often, generic companies choose to abandon their development programs for complex generic products due to this uncertainty.

A recent analysis from Matrix Global Advisors examined several of these products that have been approved in the European Union and Canada yet have experienced regulatory delays in the U.S. The analysis concludes that regulatory delays at FDA have cost American patients and the U.S. health care system over $1.3 billion annually on just seven products.[4]

We believe that, as the Agency continues GDUFA III negotiations, it is critical for the Agency to understand how important an efficient and transparent process for generic drug approval is to patients with chronic diseases who rely on medications every day. A transparent and efficient FDA process that generates the timely approvals of safe and efficacious generic medications, no matter how complex the product may be, builds confidence in the

[1] IQVIA. (2019). Fact Sheet: Generic Drug and Biosimilar Access and Savings in the U.S. Report. https://accessiblemeds.org/sites/default/files/2019-12/AAM-2019-Generic-Biosimilar-Access-Savings-US-One-Pager.pdf
[2] The Association for Accessible Medicines. (October 2020). 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report. https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf
[3] U.S. Government Accountability Office. (August 2019). GENERIC DRUG APPLICATIONS: FDA Should Take Additional Steps to Address Factors That May Affect Approval Rates in the First Review Cycle. https://www.gao.gov/assets/710/700779.pdf
[4] Matrix Global Advisors. (February 2021). Potential Savings from Accelerating US Approval of Complex Generics. https://accessiblemeds.org/sites/default/files/2021-02/Potential-Savings-Complex-Generics-Feb2021.pdf

scientific, pharmaceutical development and regulatory approval process. Further, it promotes increased competition in pharmaceutical markets and lowers the price of medications for both the patient and the U.S. health care system.

With these goals in mind, we believe this is an important opportunity to enhance the Agency's review of complex generic drugs and ensure they reach the market in a more timely way. Specifically, we call on FDA and industry to:

1. improve the quality of submissions through limiting the use of Major Complete Response Letters (CRLs) where possible, and instead, engaging in more frequent interactions with ANDA sponsors and work through a goal date if an approval is imminent to reduce unnecessary subsequent review cycles;
2. adopt better guidance practices so Product Specific Guidances (PSGs) do not inadvertently delay approvals; and,
3. minimize regulatory uncertainty by increased transparency and communication between FDA and ANDA sponsors

Increased prioritization of ANDA submissions for complex generics, particularly for those first generics on the market or where unmet need exists, may require additional resources for FDA. We believe these changes are especially critical if we are to realize the full potential of complex generic drugs for patients, the health care system and the U.S. economy.

We stand ready to assist and ensure that GDUFA III accelerates patient access to more safe, effective and affordable complex generic medicines.

Respectfully,

Advocacy & Awareness for Immune Disorders Association
Allergy & Asthma Network
Alliance for Patient Access
ASPIRE, Alliance to Solve PANS & Immune-Related Encephalopathies
Asthma and Allergy Foundation of America
Black Women's Health Imperative
Consumer Action
Friends of Cancer Research
Global Liver Institute
International Pemphigus Pemphigoid Foundation
National Alliance on Mental Illness
The National Multiples Sclerosis Society
Prevent Cancer Foundation
Sisters Network Inc.
Society for Women's Health Research

cc:
Janet Woodcock, Acting Commissioner of the Food and Drug Administration
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