Your Generics & Biosimilars Industry

WASHINGTON, DC (September 21, 2021) — Today, the U.S. Food and Drug Administration (FDA) released the performance goals letter for the third installment of the Biosimilars User Fee Act (BsUFA III). We applaud the FDA for working diligently with industry in our ongoing efforts to continue to improve the BsUFA User Fee program.

The BsUFA III performance goals letter expands on the BsUFA II goals letter, which expires at 11:59 pm on September 30, 2022. This goals letter provides for an enhanced focus on strengthening accountability and transparency as we work together to advance access for all patients.

Key elements of the BsUFA III goals letter include:

1. Supplements
    - Supplement reviews will be accelerated
        - 3 months (safety labels)
        - 4 months (extrapolation, label carve-in and carve outs)
        - 6 months (new PK data)
        - Interchangeability and efficacy supplement reviews remain at 10 months
2. Meeting management
    - BIA meetings will no longer require analytical data
    - Briefing book for the pre-BLA meeting will be due 14 days after the meeting request. This will accelerate the BLA submission process by two weeks
    - A new Type 2a meeting to obtain rapid feedback of a focused set of questions
    - A new mechanism created to obtain rapid clarification of meeting minutes
    - A program was established to share best practices related to meeting management

3. Interchangeability program
    - Research under the pilot regulatory science program
    - Foundational guidance development
        - Commitments under the umbrella of an interchangeable biologic program.
        - This was new in BsUFA II, and FDA was willing to make standalone guidance commitments
    - A workshop to obtain external stakeholder input
4. Regulatory Science Program
    - Interchangeability guidances inserted into regulatory science
    - Incorporation of specific projects into the Commitment Letter
    - A pilot regulatory science program will be established focusing on two areas, each of which will have two research projects:
        1. Interchangeable biologics
            a. The potential impact of differences between proposed interchangeable biosimilar and reference product presentations are container closure systems.
            b. Predict immunogenicity related to interchangeability (e.g., after multiple switches)
2. Improve the efficiency of biosimilar product development
            a. Streamlining biosimilar development (aka tailored biosimilar clinical development)
            b. Seeking correlates of immunogenicity
5. Financial spend-down of carryover funds (currently at 39 weeks, will work down to 21 weeks over 3 years)
6. HF / URRA – new 6-month review clock, identical to PDUFA VII goals letter
7. Remote inspections – new process, identical to PDUFA VII goals letter
8. IT – movement to the cloud, identical to PDUFA VII goals letter with no demonstration project
9. Electronic submissions gateway to be modernized, identical to PDUFA VII goals letter