U.S. FOOD & DRUG ADMINISTRATION

GDSA-BE: Modernizing Bioequivalence Assessment for Abbreviated New Drug Applications

Tao Bai
Senior Advisor

Office of Bioequivalence (OB), Office of Generic Drugs (OGD)
CDER | U.S. FDA

SBIA Generic Drugs Forum – April 10-11, 2024

We Are OGD

Ask me why...

"I make sure that the **generic** drug and the **brand** drug work **the same**."

"The first time I was able to buy my son's inhaler as a generic and realized that my out of pocket dropped, I cried and was able to breathe a sigh of relief."

www.fda.gov

Need for Modernization - Technology Advancement

Outside World

GDSA-BE

(Generic Drug Structured Assessment – Bioequivalence)

Consistency | Standardization | Efficiency

Knowledge Management

Regulatory Review

Need for Modernization- Challenges with Current Process

External

- Need for a more streamlined assessment process to better meet GDUFA* goals
- Increased expectations from Congress, generic applicants, and the public

Assessment

- A freestyle narrative-based bioequivalence (BE) assessment, which is in place for decades
- Labor intensive tasks to process data, conduct data analysis, and extract and supply standard information to the review templates
- Lack of a better practice for knowledge sharing and knowledge management

Application

- Needs for standardized and structured data submission in ANDA applications

** Generic Drug User Fee Act*

OGD Strategic Priorities (2023 – 2028)

Modernizing the Generic Drug Program

People
Foster an engaged organizational culture that attracts and retains a highly qualified, talented, and diverse workforce empowered to carry out the mission of OGD.

Process
Modernize processes to enhance efficiency and consistency across the generic drug program.

Innovation
Promote innovation and excellence to enable the efficient development and approval of safe and effective generic drug products.

Lifecycle Engagement
Champion a shared vision and understanding of drug product lifecycle for optimal use of the 505(j) pathway.

from Iilun Murphy's keynote at the AAM GRx + Biosims 2023 conference

GDSA-BE

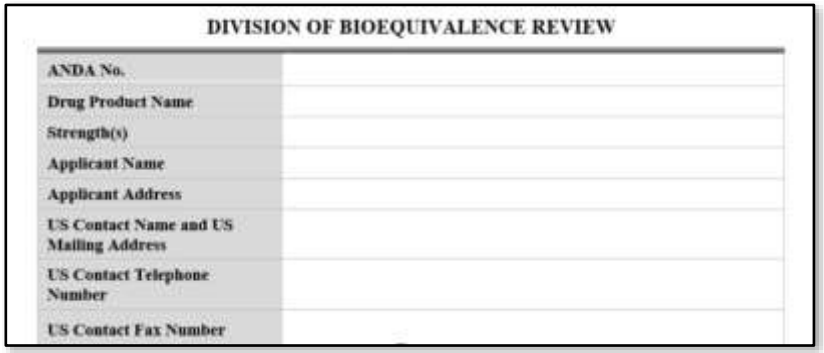
Modernizing the BE Assessment Process:

In 2023, OGD launched a new structured BE assessment tool – the Generic Drug Structured Assessment for Bioequivalence (GDSA-BE) – for two-way crossover in vivo pharmacokinetic (PK) BE studies for oral solid dosage form drug products. This tool officially signaled the change of bioequivalence assessment from narrative review to structured data with dynamic, interactive, and integrated collaboration capabilities. GDSA-BE is a BE assessment tool to enable a streamlined and efficient BE assessment and a powerful knowledge management tool, which aids consistent and well-informed regulatory decision making with direct access to multiple subject databases.

OGD Generic Drug Structured Assessment (GDSA)

-OGD Structured Review Templates in NEXUS (Appian) – *Enterprise-level solution*

Modernization of bioequivalence assessment from unstructured narrative *to* structured data with dynamic and interactive collaboration capabilities utilizing an integrated system.



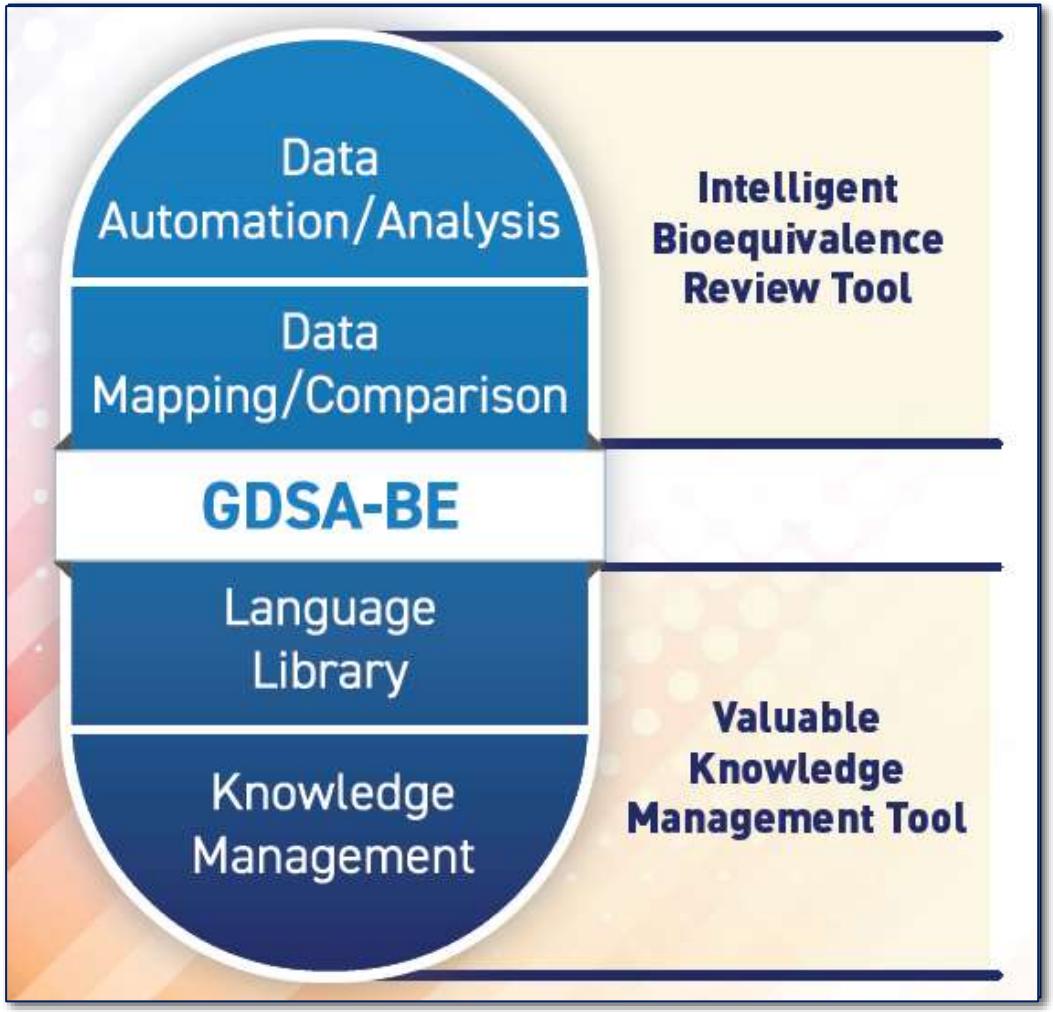
DIVISION OF BIOEQUIVALENCE REVIEW

ANDA No.	
Drug Product Name	
Strength(s)	
Applicant Name	
Applicant Address	
US Contact Name and US Mailing Address	
US Contact Telephone Number	
US Contact Fax Number	

Current BE Review- Unstructured Narrative

GDSA-BE Review-Structured and Interactive

GDSA-BE Benefits



Where is GDSA-BE Today

Releases

- V(1.0) Released on 12/12/2022
- V(1.1) Released on 9/18/2023
- V(1.2) Released on 3/25/2024

Assessments

- ~60 ANDA assessments completed in the system

Implementation

- Implemented **fully** in Office of Bioequivalence

Challenge Question

GDSA-BE *(Generic Drug Structure Assessment – Bioequivalence)* tool is (a):

A. Generic Drug BE Review Tool
B. BE Knowledge Management Tool
C. Both

Summary

- Generic drug bioequivalence assessment is entering a ***new era*** – GDSA-BE (Generic Drug Structured Assessment – Bioequivalence)
- GDSA-BE is both an intelligent review tool and a valuable knowledge management tool
- GDSA-BE enables an efficient and standardized BE assessment process and empowers an informed and consistent regulatory decision-making

FDA U.S. FOOD & DRUG ADMINISTRATION