

In accordance with the commitment in Section I.H.6.c. of the *Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027* (“BsUFA III Commitment Letter”), FDA is publishing “certain metrics regarding the new Type 2a meeting and sponsor requests for face-to-face meetings for year 1 and year 2 of BsUFA III.”

**BsUFA Type 2a Meetings and Formats Granted, FY2023-FY2024\***

Meeting Format Requested	Total Meeting Requests Assessed as Type 2a	Meeting Format Granted^				Denied**
		Face-to-Face <sup>‡</sup>	Tele-conference	WRO	Total	
Face-to-Face <sup>‡</sup>	24	13	0	11	24	0
Teleconference	32	6	15	11	32	0
WRO	23	1	0	21	22	1
Format Not Requested	2	0	0	2	2	0
<b>Total</b>	<b>81</b>	<b>20</b>	<b>15</b>	<b>45</b>	<b>80</b>	<b>1</b>

Note: Data reflects CDER+CBER, however, CBER did not have any Type 2a Meetings. FY2023 data as of 9/30/2024. FY2024 data as of 12/31/2024. Only includes meetings that were assessed as Type 2a. Does not include scenarios where meetings were requested as Type 2a but assessed as a different meeting type (e.g., Type 2b).

\*FY2024 data has been updated from what was presented in the Report to Congress. Data is preliminary and may change as the cohort matures.

\*\*For the one Type 2a Meeting denied in FY2023, the meeting was denied based on your meeting objectives, this meeting is premature for the stage of product development/protocol.

^Includes meetings granted by FDA and later canceled by the sponsor. For meetings granted as WRO, all requests were responded to.

‡As defined in the BsUFA III Commitment Letter (page 20, footnote 2), a “face-to-face” meeting includes both in-person meetings and virtual meetings on IT platforms that allow for both audio and visual communication.