Table 10.2 Volume of Biosimilar Program Submissions and Applications

Category	FY13	FY14	FY15 (First 2 Quarters)	Total
Number of sponsors in the program (cumulative totals)	33	48	52	52
Biosimilar Application Review				
Original biosimilar product applications	0	2	3	5
Resubmitted original biosimilar product applications	0	0	0	0
Original supplements with clinical data	0	0	0	0
Resubmitted supplements with clinical data	0	0	0	0
Manufacturing supplements	0	0	0	0
Procedural Notifications				
Notification of issues identified during review	0	2	3	5
Notification of planned review timeline	0	2	3	5
Review of proprietary biosimilar product names (during BPD phase)	3	3	3	9
Review of proprietary biosimilar product names (with application)	0	1	4	5
Review of proprietary biosimilar product names (resubmitted or requests for reconsideration)	0	0	0	0
Procedural Responses				
Major dispute resolution	0	0	0	0
Responses to clinical holds	1	1	2	4
Special protocol assessments	0	2	1	3
Meeting Requests				
Biosimilar Initial Advisory	4	11	2	17
BPD Type 1	0	1	2	3
BPD Type 2	21	30	21	72
BPD Type 3	6	9	1	16
BPD Type 4	1	3	1	5
Scheduled Meetings				
Biosimilar Initial Advisory	3	9	2	14
BPD Type 1	0	1	2	3
BPD Type 2	20	25	19	64
BPD Type 3	6	9	1	16
BPD Type 4	1	3	1	5
Provided meeting minutes (all meeting types)	29	42	17	88

Source: FDA, http://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm459686.pdf.

Note: FY13: fiscal year 2013; FY14: fiscal year 2014; FY15: fiscal year 2015.