"HHS/FDA Biosimilars Prescribing Survey"
(OMB Control Number 0910-0695)

November 1, 2019

This document details an issue identified after fielding of the HHS/FDA Biosimilars Prescribing Survey (OMB ICR REFERENCE NUMBER: 201712-0910-001). It will explain the context of the study, the issue identified, the issue origins, and the proposed remediation.

Summary of the study: The information collection was approved on July 11, 2019 under the generic clearance "Data to Support Drug Product Communications and Biosimilar Prescribing" (OMB Control Number 0910-0695). The survey is intended to assess healthcare professionals' likely prescribing habits for biosimilar biological products, insights which would be used to inform education and information efforts by the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA). The survey presents physicians with hypothetical prescribing scenarios and hypothetical products and examines factors including FDA's naming convention for biological products.

Issue Identified: As described in the OMB Approval Memo for the survey, which was fielded August 20, 2019 through September 14, 2019, the survey was designed to randomize stimuli in that half of the participants from each specialty would be shown the nonproprietary name of the Junexant drug with a suffix (A1) and half would be shown the Junexant drug without a suffix (A2). All participants were to be shown the nonproprietary name of Nexsymeo with a suffix (B). Upon initial analysis of the survey data, the survey vendor found that (1) a nonproprietary drug name for Junexant was not shown for any questions and (2) the randomization did not occur at all due to issue #1. Instead, survey participants saw the Nexsymeo drug with a suffix (B) and saw "Junexant (None of these Classifications Apply)", instead of being randomly assigned to see Junexant with suffix (A1) or Junexant without a suffix (A2).

Table 1: Drug Name Table

Specialty	A1: (Junexant with suffix)	A2: (Junexant without suffix)	B (Nexsymeo)
Rheumatology	Junexant (denliximab-ghvb)	Junexant (denliximab)	Nexsymeo (denliximab-kbcn)
Dermatology	Junexant (denliximab-ghvb)	Junexant (denliximab)	Nexsymeo (denliximab-kbcn)
Gastroenterology	Junexant (denliximab-ghvb)	Junexant (denliximab)	Nexsymeo (denliximab-kbcn)
Oncology	Junexant (alodripsim-ghvb)	Junexant (alodripsim)	Nexsymeo (alodripsim-kbcn)
Hematology	Junexant (alodripsim-ghvb)	Junexant (alodripsim)	Nexsymeo (alodripsim-kbcn)
Nephrology	Junexant (esalamin-ghvb)	Junexant (esalamin)	Nexsymeo (esalamin-kbcn)

Issue Origin Findings: As is standard, survey programming and data collection went through extensive, iterative rounds of quality control assessment before the survey was fielded. However, during testing-related communication between researchers and the survey programmer, changes to include identified randomization issues were noted in the annotated questionnaire and change log, but the necessary revisions were not made to the survey prior to fielding. Due to this, the correct piping for randomization did not occur, which resulted in Junexant questions being displayed incorrectly and the desired randomization not taking place in the survey.

Table 2: Impacted survey items

Impacted: *Question asks about or build on questions about Junexant or Nexsymeo*	**Not Impacted:** *Question does not ask about or build on questions about Junexant or Nexsymeo*
Q8-Q16, Q18, Q21-Q23	Q1-Q7, Q17, Q19, Q20, Q24
Total: 13 questions	**Total:** 11 Questions

Proposed Remediation: As this was an error on the survey vendor's part, the company has proposed to address this error and conduct this survey again at no charge to the government. None of the information collected in the survey as previously approved by OMB would change. FDA has made clarifying revisions to the programmer note and to the programmer piping tables in the Biosimilar Survey Questionnaire to ensure the survey design is accurately captured.

Approximately 18 participant burden hours remain from the estimated 210 hours approved for the survey. If OMB permits the reallocation of the remaining 18 participant burden hours, an estimated additional 192 hours under the generic clearance "Data to Support Drug Product Communications and Biosimilar Prescribing" (OMB Control Number 0910-0695) would be needed to complete this survey.

The survey vendor estimates that increased honoraria may be necessary to support recruitment of a new panel of survey participants. Following are the revised estimated amounts, differentiated by specialty, that will be awarded to respondents who complete the survey.

Table 3: Estimated Honoraria by Specialty

Original	Revised
Dermatology: $30.00	Dermatology: up to $60.00
Gastroenterology: $35.00	Gastroenterology: up to $45.00
Hematology: $60.00	Hematology: up to $80.00
Nephrology: $30.00	Nephrology: up to $60.00
Oncology Cancer: $35.00	Oncology Cancer: up to $80.00
Rheumatology: $40.00	Rheumatology: up to $80.00
Nurse Practitioner - Physician Assistant: $25.00	Nurse Practitioner - Physician Assistant: $25.00

As a result of the identified issue, the survey vendor is revising its quality control procedures to prevent this issue from happening again.