

U.S. Food and Drug Administration

Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites  
OMB Control Number 0910-0872

No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

**Proposed Changes**

Based on cognitive interviews and pretesting, and in accordance with the terms of approval, we propose changes to the questionnaire to improve clarity. These changes do not affect the burden estimates.

1. Deletions:

- We deleted the questions that were intended only for pretesting (Q27 and Q30). We also deleted Q11 (perceived risk), three responses from Q13 (behavioral intentions), and Q22–Q23 (familiarity with accelerated approval).
- We pretested two versions of Q12 (Q12 and Q12alt) and deleted Q12alt.
- We deleted Q21s and Q21c (cancer treatment history) from the questionnaire and moved them to the screener, where they replaced similar items (S7s and S7c).
- We deleted instructions from the end of the screener and moved them to the questionnaire, where they replaced similar instructions.

2. Updates to wording:

- We made minor changes to the study instructions (e.g., changing “website” to “webpage”).
- We added “please be as detailed and specific as possible when entering your answer in the space provided” to an open-ended item, Q3.
- We split Q14a into two items so that risks and benefits are asked about separately.
- We changed the wording in Q15a and Q15b for Study 2 from “statement” to “information.”
- We clarified in Q24c and Q25c that we are asking caregivers about current care or care provided in the past and that if they cared for more than one person, they should think of their most recent caretaking role. We also changed the categories of response options for Q25c (caregivers’ length of care).

**Dated: October 25, 2022**