

U.S. Food and Drug Administration

Study of Disclosures to Health Care Providers Regarding Data
That Do Not Support Unapproved Use of an Approved Prescription Drug
OMB Control Number 0910-0900

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

Proposed Changes

Based on the pretest, and in accordance with the terms of approval, we propose changes to the questionnaire to improve clarity, which will not change the amount of time required to complete it.

1. Deletions. We have deleted all the questions that were intended only for pretesting (Q12, Q13, Q14). We have also deleted Q2c because the pretest revealed that higher than expected numbers of participants answered Q2c incorrectly, which suggested there was confusion among participants.
2. Updates to wording: We have revised Q2e to read: The materials describe other data which does not support the use of [DRUG] for [DISEASE].
3. Format: As planned, we have revised Q18 and Q24 from open-ended to closed-ended questions. In the pretest, these questions were presented as open-ended questions. We used the provided responses to craft closed-ended responses. This is expected to save the participants' time and effort.

Q18. Where do you typically first hear or learn about an off-label use for a prescription drug? (Select your top two sources.)

- Colleagues
- Medical journals
- Google or other online search engines
- Medical reference websites such as UpToDate or Epocrates
- DISPLAY ONLY FOR ONCOLOGISTS:** National Comprehensive Cancer Network Guidelines
- Professional medical association conferences and communications
- FDA
- Pharmaceutical companies
- Online communities of physicians
- Key opinion leaders or thought leaders in the field
- Other, please specify:

24. Please rank the top three circumstances where you feel it would be most important for you to know about studies that contradict or are inconclusive about an off-label use of a drug.

Please write 1, 2, or 3 in the boxes below to rank your top three choices.

- There are safety concerns associated with the off-label use
- The patient being treated is part of a unique population (e.g., young, critically ill, etc.)
- Efficacy of the off-label use is not clearly established
- There is uncertainty about whether to prescribe the drug for the off-label use
- Contradictory studies have stronger study designs than studies supporting the off-label use
- The off-label use is common
- The off-label use, or the drug itself, is new
- There are concerns about drug interactions
- Other, please specify:

Dated: July 27, 2022