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)

This information collection supports section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)), which authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

FDA's Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that its policies related to prescription drug promotion will have the greatest benefit to public health. We have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. This study in this information collection pertains to the two topic areas: (1) advertising features and (2) target populations. Our purpose for the information collection is to examine how physicians process information about unapproved new uses of approved prescription drugs when made aware of other unsupportive information and how they evaluate the effectiveness of various disclosure approaches for this information. This study has provided and continues to provide FDA with empirical information of the effects that these variables have on physician perceptions and has informed and continues to inform FDA's regulatory approach to materials of this type.

Proposed Changes

Based on the second round of cognitive testing, we propose changes to the questionnaire to improve clarity, which will not change the amount of time required to complete it.

1. Additions. We propose to add one question to assess prior experience prescribing for the target condition.

PRESCRIBING DRUGS
Have you ever prescribed [DRUG] **for** [DISEASE]**?**
☐ Yes
☐ No

2. Deletions. Based on the second round of cognitive testing, which suggested there was little variability in responses, we have deleted Q2e and Q2f. The second round of cognitive testing also revealed that participants did not distinguish between the terms *contradict* and *inconclusive*. This is consistent with the first round of cognitive testing. Although we

originally intended to test these as separate terms in the pretest, we have determined that based on these two cognitive testing rounds, we will combine the wording into one question. Accordingly, we have deleted separate questions Q21 and Q22. The new wording reads:

> "Thinking of the studies you have seen in the past, how often have you seen study findings that contradict or are inconclusive about an off-label use of a drug?"

3. Updates to wording: We have made the following updates to improve the clarity of the questions and reduce the possibility of confusion.

   Updates to Q2 instructions: Based on the second round of cognitive testing, the instructions have been changed to read:

   > "Please indicate whether any of the following were mentioned in the materials you reviewed."

   Updated prescribing frequency categories: We have updated the categories describing frequency of prescribing drugs in Q15 to reflect the prescribing patterns described by participants in the cognitive interviews.

How often do you prescribe a drug for an off-label use?

- ☐ 1 or more times a day
- ☐ 1-6 times a week
- ☐ 1-3 times a month
- ☐ 1-11 times a year
- ☐ Less than once a year
- ☐ I have never prescribed a drug for off-label use

Revised list: We revised the list of choices to add National Comprehensive Cancer Network Guidelines, deleted the option choice online communities of physicians, and deleted one open-ended answer option, Professional guidelines (please specify), in Q18/19 and Q25.

How often do you use the following sources to learn about off-label uses for a drug?

	Never	Rarely	Sometimes	Often	Very Often
a. Colleagues	☐	☐	☐	☐	☐
b. Medical journals	☐	☐	☐	☐	☐
c. Google or other online search engines	☐	☐	☐	☐	☐
d. Medical reference websites such as UpToDate or Epocrates	☐	☐	☐	☐	☐
ASK ONLY TO ONCOLOGISTS e. National Comprehensive Cancer Network Guidelines	☐	☐	☐	☐	☐
f. Professional medical association conferences and communications	☐	☐	☐	☐	☐
g. FDA	☐	☐	☐	☐	☐

h. Pharmaceutical companies	☐	☐	☐	☐	☐
i. Online communities of physicians	☐	☐	☐	☐	☐
j. Key opinion leaders or thought leaders in the field	☐	☐	☐	☐	☐
k. Other, please specify	☐	☐	☐	☐	☐

Added descriptor to list: We added "study duration" to the existing list in Q23b because several cognitive interview participants mentioned it as important during the interviews.

How important is it to you to know about the following aspects of a study about an off-label use of a drug?

	Not at all important	A little important	Somewhat important	Very important	Extremely important
a. Study population	☐	☐	☐	☐	☐
b. Study design, e.g., randomized controlled study, observational study, study duration	☐	☐	☐	☐	☐
c. Sample size	☐	☐	☐	☐	☐
d. Findings related to safety of the off-label use	☐	☐	☐	☐	☐
e. Findings related to side effects of the off-label use	☐	☐	☐	☐	☐
f. Study sponsor	☐	☐	☐	☐	☐
g. Number of studies that contradict or are inconclusive about an off-label use of a drug	☐	☐	☐	☐	☐

Updated debriefing: We have updated the wording of the debriefing statement.

Debrief

Thank you for taking part in this survey. While the information presented is accurate, the information provided about {DRUG} and its off-label use for {CONDITION} is a combination of several different studies.

4. Format: We have updated the format of Q2 so that all items are shown together instead of one at a time in separate question parts. This is expected to save the participants' time and effort.

   Please indicate whether any of the following were mentioned in the materials you reviewed.

	Yes	No	I'm not sure
SHOW FOR ALL CONDITIONS: a. A brief report on a study that supports use of **[DRUG]** for **[DISEASE]**	●	☐	☐
SHOW FOR ALL CONDITIONS: b. A discussion of the limitations of a study that supports use of **[DRUG]** for **[DISEASE]**	●	☐	☐
SHOW FOR ALL CONDITIONS: c. A description of an experimental study design	☐	●	☐
SHOW FOR ALL CONDITIONS: d. Outcomes for a placebo group	☐	●	☐
SHOW FOR CONDITONS 1-4 ONLY: e. The use of **[DRUG]** for **[DISEASE]** has been approved by the FDA	●	☐	☐
SHOW FOR CONDITIONS 1-3 ONLY: f. The materials summarize a study whose result does not support the use of **[DRUG]** for **[DISEASE]**	●	☐	☐
SHOW FOR CONDITIONS 2-3 ONLY: g. The materials gave a citation for a study whose result does not support use of **[DRUG]** for **[DISEASE]**	●	☐	☐
SHOW FOR ALL CONDITIONS: h. Information about whether the described use of **[DRUG]** was off-label	●	☐	☐

5. Changes to informed consent language: Westat's Institutional Review Board requested a minor change in wording to one part of the Informed Consent.

Rights as a Participant

This study is voluntary. You do not have to answer any questions that you do not want to and can withdraw from the study at any time. The Institutional Review Board at Westat has reviewed this research study. If you have questions about your rights and welfare as a research participant, please call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your first name, the name of the research study that you are calling about (FDA Communication about Data), and a phone number beginning with the area code and someone will return your call as soon as possible.

Dated: February 3, 2022