

U.S. Food and Drug Administration  
Text Analysis of Proprietary Drug Name Interpretations

OMB Control Number 0910-0910

## **Request for Non-Substantive Change**

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) is seeking OMB approval of non-substantive change to OMB control No. 0910-0910. This information collection adds depth and breadth of knowledge drawn from review of proposed proprietary drug names. The proposed modifications to the approved information collection study design and materials based on findings from pretesting and in accordance with the terms of clearance. These modifications are intended to reduce participant burden and increase participant engagement. The revised materials are attached, and the proposed changes to these materials and to the study design are summarized below. FDA is not requesting changes to the burden hours for this information collection.

### **Summary of the Change Request (summarized by document)**

The following are proposed modifications to Text Analysis Study Screeners (Consumer and Health Care Provider):

1. **Paperwork Reduction Act Statement (Consumer and Health Care Provider)**
  - a. The existing language removal of duplicate information pertaining to the OMB control No. and expiration date of the information collection
2. **Occupation**
  - a. Revise “Pharma Rep” to “pharma representative” (Consumer)  
Revise “Research Firm” to “research firm” (Health Care Provider)
3. **Familiarity with Foreign Languages (Consumer and Health Care Provider)**



Revise the “languages” question on the screener to assess only proficiency/fluency, thus reducing participant burden
4. **Medical Condition Diagnosis (Consumer and Health Care Provider)**
  - a. Alphabetize the order of the medical condition diagnosis list in the screener, as opposed to randomizing the order as originally planned, to reduce participant burden.
  - b. Revise “Heart burn” to “Heartburn”

The following changes have been made to Text Analysis Study Questionnaire:

1. **Paperwork Reduction Act Statement (Consumer and Health Care Provider)**
  - a. The existing language removal of duplicate information pertaining to the OMB control No. and expiration date of the information collection
2. **Insertion of Prompt**
  - a. Add prompts to remind participants to answer any skipped questions. This strategy is anticipated to promote engagement with the questions and therefore increase the amount of text available for analysis
3. **Revision of Study Design**

- a. Revise the study design from 10 blocks of 12 names each to 30 blocks of 4 names. Thus, participants will respond to 4 drug names each, rather than 12 as originally planned, reducing participant burden and potentially increasing participant engagement
- 4. **Edit to Instructions**
  - a. Removal of “General impressions” and rephrase instructions to read: “As you answer, please consider your general impressions and the following features of the drug...”

**Table of Attachments**

Document Name	Track Changes
Text Analysis Study Screeners	 Screener Text Analysis PDN tracked_
Text Analysis Study Questionnaire	 Questionnaire Text Analysis PDN tracked_

Dated: June 2023