

United States Food and Drug Administration
Adverse Event, Product Experience, and Safety Reporting –
Electronic Submissions

OMB Control No. 0910-0645

Non-Substantive Change Request for CTP Safety Reporting Portal Questionnaire

The Food and Drug Administration is requesting a non-substantive change request to OMB Control No. 0910-0645, which supports adverse event, product experience, and safety reporting associated with FDA-regulated products. The Safety Reporting Portal (SRP) is one of the systems we developed to collect data electronically. The SRP enables industry, health professionals, consumers, and others to report adverse events or problems associated with regulated products by completing web-based rational questionnaires (RQ) tailored to product categories. The information submitted through the SRP is routed to appropriate FDA components so that we have real time access to reports and are able to more rapidly analyze safety problems.

Below are proposed modifications to the rational questionnaire associated with tobacco products. We believe these revisions improve the clarity of the information being collected and will allow for corresponding technical enhancements that will facilitate FDA response. We are also proposing to remove certain questions previously approved that our evaluation suggests do not add to the utility of the information collection. By removing the questions we hope to further minimize burden on respondents.

1. Change "health-related problem" to "health problem" throughout
2. Revise LOV for "Type of Attachment." One list for all CTP reporters.
3. Make optional - "Description of Attachment" and its associated free-text box.
4. Add four new values to "Healthcare Professional Type" and make it required.
5. Increase character limit on two fields (from 200 to 1000). Fields: "Describe who the problem was reported to" and "Additional notes about this report."
6. Update text on Introduction page to provide clarification for reporters
7. Under race – Add value of "other"
8. Add a new question about the event location: "In what setting(s) did this problem occur?" (not required)
9. Change "Birth defect" value to "adverse pregnancy outcome including birth defects." Remove "Emergency room visit without hospital admission."
10. Treatment Received (select all that apply): Add: "Emergency room visit without hospital admission."
11. Ability to deselect selections before saving.
12. Remove Cancel and Reactivate options from Follow-up reasons.
13. To help assure that registered reporters receive the SRP confirmation e-mail add the following line to the Report Submission Confirmation Page: Please contact SRPSupport@fda.hhs.gov, if you don't receive a confirmation email from noreply.safetyreporting@hhs.gov.
14. "FDA-assigned protocol number" - change from not required to a required field.

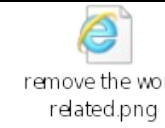
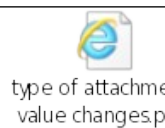
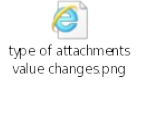
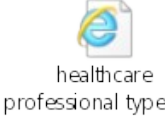

15. Remove “Health problem” language from the following questions: How soon after the tobacco product was last used did the [health-delete] problem occur? And "Did this same or similar [health-delete] problem happen again after repeat use of the tobacco product?"

16. Remove: Three questions on how FDA may share reporter identity with manufacturer/distributor, federal / state/local agencies. Retain the “did you report the problem to the manufacturer?” question.

17. Remove: Do you think this problem was caused by a particular package or unit of this product? (Yes or No)

18. Remove: In your opinion, how likely is it that the tobacco product part is related to the problem?

Summary of Changes to CTP’s Questionnaire in the Safety Reporting Portal (OMB No. 0910-0645)

Item Number	Description	Addition or Deletion	Edit	Rationale	Example	Prior Approval Given by OMB
1	Change wording		X	In the questionnaire, the term “health-related problem” occurs a couple times. We are removing the word “related” so it just reads “health problem”. This makes the item more specific to the end user.	 remove the wo related.png	Original item approved previously
2	Change a list of values		X	Change the “Type of Attachment” List of values (see attached screenshot). This provides a more complete set of choices to the end user.	 type of attachme value changes.p	Original item approved previously
3	Change from required to optional		x	Change “Description of Attachment” field from required to optional. –Less burden on reporter.	 type of attachments value changes.png	Original item approved previously
4	Change a list of values		x	Add four new values to “Healthcare Professional Type” to make choices more specific for reporter.	 healthcare professional type	Original item approved previously
5	Increase character limit on two fields (from 200 to 1000).		x	Fields: “Describe who the problem was reported to” and “Additional notes about this report.” This allows report the ability to provide more specific information		Original item approved previously
6	Update text on Introduction page	Addition		Include chart (see screenshot) to provide clarification for reporters.	 issues to repor elsewhere.png	Original item approved previously

Item Number	Description	Addition or Deletion	Edit	Rationale	Example	Prior Approval Given by OMB
7	Update Race values		x	Under race – Add value of “other” to allow for better reporting statistics		Original item approved previously
8	New question	Addition		Add a new question about the event location: “In what setting(s) did this problem occur?” (not required)—this allows CTP to better understand the context of the Adverse Event		
9	Change list of values		X	Change "Birth defect" value to "adverse pregnancy outcome including birth defects." Remove “Emergency room visit without hospital admission.” Changes will provide CTP more appropriate data points		Original item approved previously
10	Change list of values	x		Under Treatment Received (select all that apply): Add: “Emergency room visit without hospital admission.” Changes will provide CTP more appropriate data points		Original item approved previously
11	Ability to deselect selections before saving.			Currently, a reporter cannot unselect items once selected. This change allows users the opportunity to make corrections to their report		Original item approved previously
12	Change list of values		x	Remove Cancel and Reactivate options from report “Follow-up” reasons. These are not appropriate values for reporter selections.		Original item approved previously
13	Change message that is sent to reporters		x	To help assure that registered reporters receive the SRP confirmation e-mail add the following line to the Report Submission Confirmation Page: Please contact SRPSupport@fda.hhs.gov , if you don’t receive a confirmation email from noreply.safetyreporting@hhs.gov .		Original item approved previously
14	Change question from optional to			"FDA-assigned protocol number" - change from not required to a		Original item

Item Number	Description	Addition or Deletion	Edit	Rationale	Example	Prior Approval Given by OMB
	required			required field. This value is needed to associate adverse events to FDA research protocols.		approved previously
15	Change wording		x	Remove "Health problem" language from the following questions: How soon after the tobacco product was last used did the health problem occur? And "Did this same or similar health problem happen again after repeat use of the tobacco product?" This is a more appropriate way to present this question.		Original item approved previously
16	Remove questions	Deletion		Remove: Three questions on how FDA may share reporter identity with manufacturer/distributor, federal / state/local agencies. Retain the "did you report the problem to the manufacturer?" question. Unnecessary data points, decrease burden on reporter.		Original item approved previously
17	Remove question	Deletion		Remove: Do you think this problem was caused by a particular package or unit of this product? (Yes or No) Unnecessary data points, decrease burden on reporter.		Original item approved previously
18	Remove question	Deletion		Remove: In your opinion, how likely is it that the tobacco product part is related to the problem? Unnecessary data points, decrease burden on reporter.		Original item approved previously

Dated: October 2018