

Individual Interview Study of Healthcare Provider Perceptions of Boxed Warnings

OMB Control Number 0910-0695

Justification Memorandum for Non-Substantive/Non-Material Change:

FDA is submitting this nonmaterial/non-substantive change request in order to allow recruitment following the panel provider's standard policy of paying individuals who complete the study screener survey but who are deemed either a) ineligible (based on their responses to the screener survey) or b) not interested in participating in the main study interview (based on their voluntary termination of the screener survey). This policy was inadvertently omitted from the original OMB justification statement. Participants who complete at least five questions of the screener survey and are deemed either ineligible for or not interested in participating in the main study will receive a payment of \$5. This small payment will be given as a token of goodwill toward panel engagement as it is well understood that healthcare providers are a highly specialized and difficult recruit (as documented in our supporting statement). We anticipate that approximately 50 participants will receive this \$5 payment. No other changes will occur; all screener respondents and study participants will see the same email, screener, and informed consent materials. The respondent burden and all other study procedures are otherwise identical.