

United States Food and Drug Administration

Qualitative Feedback on Food and Drug Administration Service Delivery

OMB Control No. 0910-0697

SUMMARY OF GEN ICs

Title of Gen IC	Participants	How the Information Was Used	Hours Used
(CVM) Survey to Determine Euthanasia Practices and Use of Pentobarbital Among Veterinarians Practicing in the United States	2,093	The information collected helped inform CVM how best to handle communication and outreach regarding pentobarbital use and carcass disposal.	349
(CDRH) Accreditation Scheme for Conformity Assessment Accreditation Body Training Feedback	34 participants, technical assessors who work for accreditation bodies and were in attendance at CDRH's ASCA Accreditation Body training session.	Although we do not currently have plans for additional similar training sessions, we will consider this feedback in planning any future training on this topic.	3 hours total
(OC) Assessments of Patient and Patient Advocate Experience with the FDA For Patients Website and Patient Listening Session Program	142	Feedback used to demonstrate the value of FDA Patient Listening Sessions and enhance future Patient Listening Sessions to be even more useful to review staff and patients / patient groups / caregivers / advocates going forward.	25
(CTP) This is Our Watch Retailer Feedback Study	120 participants included clerks, managers, and owners of tobacco retailers.	Used feedback from retailers about their awareness, preferences and experiences related to retailer education materials and the updated minimum legal purchase age to inform updates to This is Our Watch materials.	50

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(CVM) Environmental Scan	36 respondents who interact with CVM routinely including.	The information gives CVM external perspective necessary for us to capitalize on identified strengths, address our weaknesses, and keep pace with emerging trends	5
(CBER) Strengthening Interactions Between CBER's Office of Tissues and Advanced Therapies and Cell and Gene Therapy Sponsors	30 participants were employees of cell and gene therapy product sponsors.	Information from this collection was used to identify existing areas of strength as well as areas of improvement to facilitate effective collaboration and communication between FDA CBER and cell and gene therapy product sponsors.	45
(CTP) Educational Outreach Focus Groups with Health Educators	378 participants comprised of adult health education teachers at the middle and high school level.	Information from this collection was used to improve CTP's current tobacco education and prevention materials to better serve the resource needs of middle and high school teachers in educating students about the harms of tobacco use.	212
(OC) Patient and Caregiver Diversity in FDA Patient Engagement Activities - Interviews	23 participants aged 18 and above, 13 patients with food allergy, 2 caregivers who are involved in the delivery of care to food allergy patients, and 5 representatives of food allergy patient advocacy organizations.	Information collected helped inform FDA's understanding of patients/caregivers and patient organizations engagement experiences and the heterogeneity in food drug allergy development. In addition, findings helped identify opportunities to promote diverse representation in patient engagement across the different stages of therapeutic development.	23

Title of Gen IC	Participants	How the Information Was Used	Hours Used
(CTP) Email Survey Audience Analysis Study	Participants are those that actively opted in to subscribe to at least one of FDA CTP's three email communications.	The information collected was used to expand and refine knowledge of the CTP email subscriber base to improve CTP email communications.	537
(CDER) Consumer Decision-Making Regarding Sunscreens – Interviews - Phase I	26 respondents, including adult men and women (aged 18+), of varying racial/ethnic and educational backgrounds, completed cognitive interviews in Phase 1.	Results from the cognitive interviews informed a draft report submitted to FDA (2023, June 14) for internal review titled, Consumer Decision-making Regarding Sunscreens: Findings from Phase 1 Cognitive Testing. Research findings will also inform FDA CDER's efforts to use qualitative methods to examine consumer perceptions, decision-making, and purchasing behaviors associated with sunscreen labeling (both in person and through e-commerce).	28

Title of Gen IC	Participants	How the Information Was Used	Hours Used
<p>(CDER) Small Group Discussions with Applicants and Other External Stakeholders Regarding Clarity, Understandability, and Usefulness of FDA's Benefit-Risk Framework (BRF)</p>	<p>325 participants in two groups: whose NME NDA or original BLA were received between June 1, 2020, and May 31, 2021, and non-applicant external stakeholders who may use the information in the BRF.</p>	<p>Data helped FDA improve the implementation of the BRF moving forward. Specifically, understanding the extent to which the frameworks developed by FDA were clear, understandable, and useful to applicants and other external stakeholders will assist FDA in modifying the framework to meet the needs of these audiences.</p> <p>This data collection is also part of a larger project that involves a detailed review of the BRF documents created by FDA staff and in-depth small group discussions with FDA staff on implementing and integrating the BRF into review processes. Information collected from applicants and other external stakeholders will complement internal perspectives on the framework to provide a broad assessment of the Framework's integration and implementation.</p>	<p>488</p>

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<p>(CDER)  Small Group Discussions with Applicants and Other External Stakeholders Regarding Clarity, Understandability, and Usefulness of FDA's Benefit-Risk Framework</p>	<p>Participants in the group interviews comprised staff of drug companies who had a new drug application recently approved. A total of 91 individuals participated across the 23 group interviews. The individual interviews were conducted with patients/patient advocates (34) and healthcare providers(16).</p>	<p>Results from the group and individual interviews informed the third-party evaluation of FDA's Benefit-Risk Framework for New Drug Review. Specifically, this data collection enabled inclusion of input from external stakeholders into the evaluation. This evaluation an FDA commitment under the sixth authorization of Prescription Drug User Fee Act (PDUFA). The results of the evaluation are being used to inform improvements to the implementation of the Benefit-Risk Framework.</p>	<p>212</p>