

United States Food and Drug Administration
Generic Clearance: Customer Satisfaction Surveys
OMB Control Number 0910-0360
Gen IC Request for Approval

Title of Gen IC: CDER NextGen Portal Survey to System Users (CDER/Office of Business Informatics (OBI))

1. Statement of Need

The CDER NextGen Portal represents a significant advancement in streamlining over 25 regulatory and non-regulatory submission types (e.g. pre-assignment requests, research IND submissions, drug shortages notifications, public drug shortages, controlled correspondences, meeting requests, drug development tool submissions, etc.). By enabling industry relevant parties to make non-eCTD (electronic common technical document) submissions (submission that are not in the standard format for submitting applications, amendments, supplements, and reports to the FDA), the portal significantly alleviates the operational burden by minimizing data entry and avoiding incomplete submissions. The portal also helps reduce associated costs traditionally involved in submitting documentation to the FDA, by avoiding purchasing of solutions to complete forms or paying for postage to send package to reviewers. This innovative approach not only facilitates a smoother submission process compared to email or mail submissions as the user interface of the portal will require the user to enter all data elements, which enhances the efficiency and avoids having FDA reviewers having to reaching out to the user for more information.

Furthermore, the integration of a survey within the portal will play a crucial role in gauging user satisfaction. This feedback mechanism is vital, as it will provide direct insights into user experiences and satisfaction levels, thereby guiding continuous improvements to the portal. The ultimate aim is to refine the portal's functionality, making it increasingly user-friendly and effective for all relevant parties involved.

2. Intended Use of the Information

The inclusion of a feedback survey on the CDER NextGen Portal is a strategic initiative aimed at enhancing the portal's value and functionality for its users. By systematically capturing and analyzing user feedback, our team can pinpoint specific areas of the portal that may require improvements or additional features. This direct input from users is invaluable as it allows us to align our development priorities with the actual needs and experiences of the end-users. Utilizing this feedback, we can make more informed decisions during our regular deployment cadences, ensuring that each update not only addresses user concerns but also enriches their overall experience with the portal. This ongoing cycle of feedback and improvement will enable us to continually refine the portal, thereby increasing its effectiveness and the satisfaction of its users, fostering a more productive interaction with the FDA. This strategic feedback collection will empower us to tailor the portal's functionalities to better meet the specific needs of each user group, thereby optimizing their interaction with the FDA and enhancing overall user satisfaction.

3. Description of Respondents

Respondents to the survey will be CDER NextGen Portal users. Currently, the portal

accommodates a variety of user types, including pharmaceutical companies, biotechnology firms, medical device manufacturers, clinical research organizations, regulatory affairs consultants, patients, and healthcare professionals which may capture a wide spectrum of user experiences and expectations.

4. How the Information is Collected

The survey will be embedded into the CDER NexGen Portal through the following URL (<https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission>) which does not require account creation.

5. Confidentiality of Respondents

The information gathered will be used only internally for general service improvement and program management purposes. It is not intended for substantially informing influential policy decisions, nor is it for publication or release outside FDA.

We plan to also include the following disclaimer in the survey:

“Your participation / nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection will be kept secure to the fullest extent allowed by law.”

6. Amount and Justification for Proposed Incentive

No incentive will be offered.

7. Questions of a Sensitive Nature

Since the survey will focus completely on customer experience and impressions, no questions will be of a sensitive nature.

8. Description of Statistical Methods

We do not plan to use formal statistical methods. This is an optional, web-based survey data collection.

9. Burden

Type of information collection/Category of Respondent	No. of Respondents per year	Participation Time (minutes)	Total Burden (hours)
Website Satisfaction Survey	8,500	2	255

10. Date(s) to be Conducted

December 2024 - October 2027

11. Requested Approval Date

December 2024

12. FDA Contacts

Program Office Contact	FDA PRA Contact
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