Request for Approval under the "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery" (OMB Control Number: 0910-0697)

A. TITLE OF INFORMATION COLLECTION: Assessments of Patient and Patient Advocate Experience with the FDA *For Patients* Website and Patient Listening Session Program

1. PURPOSE:

   The FDA Office of Patient Affairs (OPA) goal is to coordinate and support patient engagement activities across the medical product centers to facilitate awareness and collaboration with patient stakeholders (patients, caregivers, patient groups, and patient advocates). OPA is a group within the FDA that is actively seeking the input of individuals within and outside of the FDA on a number of high potential projects that can enhance the quality of formal and informal mechanisms by which the FDA engages with its end customers—our patients.

   The *For Patients* website and FDA Patient Listening Session program are two tools through which OPA seeks to meet this goal, and ultimately, meet the needs of patients as best as possible.

   1. The *For Patients* website is the primary intended vehicle by which patients can: (i) explore what the FDA does; (ii) look for information on treatment options and products; and (iii) engage the FDA through various formal and informal mechanisms, including the Patient Listening Sessions.
   2. The FDA Patient Listening Session Program is a vehicle to efficiently and effectively receive input from patients and their advocates on disease and treatment burden. The Patient Listening Sessions are intended to complement existing processes of getting patient input and engagement at the FDA, such as the FDA Patient Representative Program, the Patient-Focused Drug Development (PFDD) and the CDRH Patient Engagement Advisory Committee (PEAC).

   The purpose of this research is two-fold:

   1. Define recommendations for the future state of the *For Patients* section of FDA.gov that more closely aligns with the needs of patients and their advocates.
   2. Building on the existing model, understand what aspects of the current Patient Listening Session design work well, and isolate, through engagement with participants, including patients, caregivers, and their advocates, a portfolio of recommendations to enhance the sessions' value moving forward.

   The desired impact is three-fold:

   1. **Strengthen FDA's outward facing website** *For Patients* to ensure it is discoverable, consumable, and actionable in order to best serve the Office of Clinical Policy and Programs patient audiences.

2. 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.
3. **Further build and strengthen OPA's ability to support** the programs' patient engagement on cross-cutting topics.

The intended use of information is to inform the design of the *For Patients* website and the FDA Patient Listening Sessions. Both tools will increase the ease, efficiency, and effectiveness with which patients can engage with the FDA and with which the FDA can engage patients for concrete input on appropriate topics, encouraging two-way communication.

For Patients website:
The information for the *For Patients* website will reveal what users and potential users want, expect from, and are currently able to achieve by accessing the FDA website. In order to best serve patient needs, OPA will have patient stakeholders review and provide feedback on a new potential website structure, content and patient-friendly language. The information will reveal: (i) content or feature gaps on the website; (ii) problems with information architecture or how the content on the site is structured and how pages are laid out relative to one another; (iii) problems with how users engage with the structure; and; (iv) problems with the quality and accessibility of the content. These content gaps, information architecture problems, and navigation and accessibility problems will inform recommendations that will be subsequently prioritized and incorporated into a redesign of the website.

FDA Patient Listening Sessions Program:
The feedback from the FDA Patient Listening Sessions will reveal what participants expect and want from the Patient Listening Sessions and will include an assessment of the experience itself. This information will inform concrete recommendations on how to improve the structure and format as well as the content intended to be captured through the Patient Listening Sessions.

The information from the follow-up survey which is distributed to patient and caregivers participants of Patient Listening Sessions will inform OPA staff about the level of satisfaction that participants have post-participation. The survey can be used to identify whether there are additional needs the patients have and can inform any follow-up communications.

2. DESCRIPTION OF RESPONDENTS:

The target market would be patients, caregivers, patient groups, and patient advocates. Specifically, patients would be potential or historical users of the *For Patients* website and either historical or prospective participants in Patient Listening Sessions.

3. TYPE OF COLLECTION: (Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software)
[ ] Focus Group
[x] Customer Satisfaction Survey
[ ] Small Discussion Group
[ ] Other:

4. CERTIFICATION: Please read the certification carefully. If you incorrectly certify, OMB will return the generic as improperly submitted or it will be disapproved.

I certify the following to be true:

a) The collection is voluntary. Yes
b) The collection is low-burden for respondents and low-cost for the Federal Government. Yes
c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies. Yes
d) The results are not intended to be disseminated to the public. Yes
e) Information gathered will not be used for the purpose of substantially informing influential policy decisions. Yes
f) The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future. Yes

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To assist review, please provide answers to the following question:

5. PERSONALLY IDENTIFIABLE INFORMATION (PII): Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.

a) Is personally identifiable information (PII) collected? [x] Yes [ ] No
b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [x] No
c) If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [ ] No

6. GIFTS OR PAYMENT: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [x] No

BURDEN HOURS: Identify who you expect the respondents to be in terms of the following categories:

(1) Individuals or Households;
(2) Private Sector;
(3) State, local, or tribal governments; or
(4) Federal Government.

Only one type of respondent can be selected per row.
No. of Respondents: Provide an estimate of the Number of respondents.
Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)

7. BURDEN**:** Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Individuals or Households: *For Patients* website assessment	14	60	14
Individuals or Households: Patient Listening Sessions Satisfaction Survey	128	5	10.7
Totals	142		24.7

8. FEDERAL COST: There is NO estimated annual cost to the Federal government.

B. STATISTICAL METHODS

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents: Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[ ] Yes [x] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. We will use a database of known patient and patient advocate contacts maintained by the Office of Patient Affairs to identify eligible individuals for the *For Patients* website analysis; no screening will be necessary, as individuals are known to the FDA. Similarly, the Patient Listening Sessions Satisfaction Survey sample will be patients and patient advocates who participate in Patient Listening sessions. No screening will be necessary, as individuals are known to the FDA. Individual assessments will be conducted to meet target numbers as defined below.

We will conduct a total of 14 individual assessments or interviews for the *For Patients* website analysis and up to 128 individual assessments or interviews for the Patient Listening Session assessment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.

1. How will you collect the information? (Check all that apply)

    [x] Web-based or other forms of Social Media
    [x] Telephone
    [x] In-person
    [ ] Mail
    [ ] Other, Explain

Given the ongoing COVID-19 public health emergency, the Office of Patient Affairs will conduct this survey using any mitigating steps required to protect participants. All survey data will be collected from participants via web and telephone. Any in-person data collection will be conducted only when it is safe to do so.

2. Will interviewers or facilitators be used? [x] Yes [ ] No

Please make sure that all instruments, instructions, and scripts are submitted with the request. Described below with appendices included.

The information for the website and Patient Listening Sessions will be captured through retrospective and prospective interviews that focus on users' experience navigating the website or participating in a Patient Listening Session. The information gathered will be qualitative in nature, focusing on the expectations, needs, opinions, and utility of the experiences. The information will be complemented by evaluative metrics on understandability, utility, and experience. Open-ended questions will allow us to gather more qualitative information to have a better understanding of the user's or participant's needs and develop more specific recommendations for either the *For Patients* website or for the Patient Listening Sessions.

Appendices included
Appendix I: *For Patients* Website Interview Guide
Appendix II: Patient Listening Sessions Satisfaction Survey

REQUESTED APPROVAL DATE: January, 2021

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