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, Patient Listening Sessions, and Patient Affairs Staff Inquiry System

1. PURPOSE:

   The FDA Patient Affairs Staff (PAS) goal is to coordinate and support patient engagement activities across the medical product centers to facilitate awareness and collaboration with patients and their advocates. PAS is a new 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, patient Listening Sessions, and PAS Inquiry System are three tools through which PAS 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 Listening Sessions.
   2. The patient Listening Sessions are a vehicle for efficiently and effectively receive input from patients and their advocates on disease and treatment burden. The Listening Sessions are intended to complement existing more formal 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).
   3. The PAS Inquiry System seeks to streamline the manual process of data calls for each medical product center to better determine external inquiry volume type and outcomes results of patient inquiries to the FDA. The lack of a solitary system to support these patient inquiries causes inefficiencies in single requests being addressed by multiple people. Requests sent through multiple intake points can create risk for inconsistent information and duplication of work. Lastly, there is no data or information on the number, type, or performance in addressing these inquiries and/or meeting requests.

   The purpose of this research is three-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 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.
3. Test the design of a patient inquiry system that auto-routes requests to the suitable center by using agreed upon business rules.

The desired impact is four-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 Medical Products and Tobacco patient audiences.
2. Demonstrate the value of the patient Listening Sessions and **enhance future listening sessions to be even more useful to** review staff and patients / caregivers / advocates going forward.
3. **Better manage FDA communication and interactions with patients**, while also developing precise and accurate responses to patient inquires and fulfilling meeting requests with appropriate center representation.
4. **Further build and strengthen PAS' 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, the patient Listening Sessions, and the PAS Inquiry System. All three 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 as envisioned by the Commissioner.

For Patients website:
The information for the *For Patients* website will reveal what users and potential users want and expect from and are currently able to achieve by accessing the FDA website. 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.

Patient Listening Sessions:
The information for the patient Listening Sessions will reveal what participants expect and want from the 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 of as well as the content intended to be captured through the Listening Sessions. It will be incorporated into a structured procedures document that codifies the Listening Sessions process, from evaluation through preparation and the actual conduction of the session, to its evaluation and outputs. This procedures document will be modeled off of the FDA's Staff Manual Guides and will be iteratively modified after subsequent Listening Sessions until the end of the project.

PAS Inquiry System:
The information for the PAS Inquiry System will also inform how to route patient inquiries to appropriate centers based on what they have completed on their submission form. The system's intended use is to better communicate with patients and fulfill their specific needs by providing support and guidance from PAS or the appropriate medical product centers.

The system will provide an infrastructure for the set-up, performance and monitoring of patient engagement activities. Additionally, the system will only capture new patient interactions. Therefore, the system does not replace existing connections and intake points, but rather streamlines them. Lastly, the system will provide users the ability to add or change business logic without requiring code development. Safeguards are established within the system to evaluate the change's effect on other rules in the system and notifies end users of any conflict.

2. DESCRIPTION OF RESPONDENTS:

The target market would be patients, caregivers, patient groups, and patient communities. Specifically, patients would be potential or historical users of the *For Patients* website, either historical or prospective participants in Listening Sessions, or patients looking for answers to inquiries and/or to set up meetings with FDA.

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	[x] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software)	[ ] Small Discussion Group
[ ] Focus 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 <u>not</u> raise issues of concern to other Federal Agencies. Yes
d) The results are <u>not</u> intended to be disseminated to the public. Yes
e) Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> 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	5	105	8.75
Individuals or Households: Patient Listening Sessions assessment	12	75	15

Individuals or Households: PAS Inquiry System Questionnaire Webform	50	3	2.5
Individuals or Households: PAS Inquiry System Feedback Survey	50	5	4.25
Totals	117		30.5

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. A third party contractor will use a database of known patient and patient advocate contacts maintained by the Patient Affairs Staff to identify eligible individuals for the *For Patients* website analysis; 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 5 individual assessments or interviews for the *For Patients* website analysis, up to 12 individual assessments or interviews for the Listening Session assessment, and seek up to 50 respondents to the PAS Inquiry System Questionnaire Webform and feedback survey during a user testing phase (prior to deployment).

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

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 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 Listening Sessions.

The information for the PAS Inquiry System will be collected by using a 10-questionnaire webform located on the FDA.gov website. There will be close-ended questions, such as user association as either an individual patient or patient group, whether the submission is an inquiry or meeting request, and the patient's preferred method of contact. Furthermore, users can choose specific programs and medical product types from a provided list that he or she is interested in discussing. The rest of the information provided will be from open-ended questions as a free text setup. This includes type of disease, medical product types, descriptions for further understanding the request, and relevant URL's. Open-ended questions allow the recipient to gather more qualitative information to have a better understanding of the user's needs and can better asses the request.

An 8-question feedback survey will be administered to users of the webform and will contain open-ended questions that seek feedback on user experience with the webform.

Appendices included
Appendix I: *For Patients* website Interview Guide
Appendix II: Patient Listening Sessions Interview Guide
Appendix III: PAS Inquiry System Questionnaire Webform
Appendix IV: PAS Inquiry System Feedback Survey
Appendix V: PAS Inquiry System Questionnaire Webform Screenshot

REQUESTED APPROVAL DATE: October, 2018

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