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: Patient and Caregiver Diversity in FDA Patient Engagement Activities - Interviews

1. PURPOSE:

   The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. To better understand the current makeup of patients providing input regarding a specific disease or therapeutic area involving FDA-regulated products, the team will conduct in-depth interviews with patients, caregivers, and patient advocacy organization representatives with experience with food allergy to explore what patient and patient organization factors influence participation in FDA patient-engagement programs (e.g., patient-focused drug development meetings, listening sessions) and factors most associated with engagement strategies and obtaining broad patient representation and help identify opportunities to promote diverse representation in patient engagement across the different stages of therapeutic development.

   The FDA will use the information collected during these individual interviews to help inform its understanding of patient and caregiver engagement and its heterogeneity in food allergy drug development and to help identify opportunities to promote diverse representation in patient engagement across the different stages of therapeutic development. FDA hopes to increase our understanding of patient and patient organizations experiences with engaging with the FDA in food drug allergy development.

2. DESCRIPTION OF RESPONDENTS:

   Participants in the individual interviews will be drawn from: (a) patients with food allergy; (b) caregivers who are involved in the delivery of care to food allergy patients; and (c) food allergy patient advocacy organization representatives.

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	[ ] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software	[ ] Small Discussion Group
[ ] Focus Group	[x] Other: Individual Interviews

Interviews will take place virtually via Zoom during November 2021, December 2021, January 2022, February 2022

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.
b) The collection is low-burden for respondents and low-cost for the Federal Government.
c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies.
d) The results are not intended to be disseminated to the public.
e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.
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.

Name: Christine Lee

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? [ ] Yes [X] 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.

Patient, caregiver, and patient organization representatives will be provided a gift card of $75 as a token of appreciation for participation (approximately 90 minutes). These amounts were determined based on average hourly wages among residents of the DC/MD/VA Area. Additional justifications for providing the dollar amount in compensation are included below:

- The payment is intended to recognize and thank each participant for taking the time to answer the questions as honestly as possible.

- As standard practice in commercial market research, and as has been approved by OMB in the past, focus group participants may be offered an incentive at a regionally appropriate market rate (usually $50 to $75) as remuneration. This was stated in the Data to Support Drug Product Communications project (OMB Control No: 0910-0695)

- In the Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery (OMB Control No: 0910-0697) renumeration (usually $40 to $75) for participating in focus groups to gather qualitative information on FDA service delivery efforts. This information is necessary to enable FDA to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with the agency's commitment to improving service delivery.

- These amount of $75 was assessed based on the average hourly compensation for effort and time that The University of Maryland PATIENTS Program has used for similar projects in the past and that were recommended by the National Health Council (NHC), which works with a plethora of patient organization and other stakeholders in conducting qualitative research projects that provide renumeration to participants.

- OMB approved the "Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates: and Risk Factors: Improving the Safety of the U.S. Blood Supply Through Hemovigiliance" Study (OMB control number 0925-0630) cases were provided $75 as a token of appreciation. Using the US BLS inflation calculator, $75 in 2010 dollars is $90.54 today. As we will conduct interviews over the next several months (2021-2022), we want to be certain to provide a token of appreciation consistent with inflation-adjusted amounts and trends and to reflect the importance of each interviewees time[1].

- A review of epidemiologic studies on food allergies identified that racial/ethnic differences among patients with food allergies relate to access to specialists and follow-up healthcare, as well as food security (Warren et al., 2021). For example, the prevalence and burden of food allergy is consistently higher in Black children relative to white children; even when adjusting for income and education (Warren et al., 2021). Furthermore, racial and ethnic minorities have historically been underrepresented in clinical trials for clinical therapies as a whole; and this still remains an issue today (Clark et al., 2019). Some barriers to participating in drug development initiatives include, but are not limited to: mistrust, lack of comfort with the clinical trial process, lack of information about clinical trials, time and resource constraints associated with participation, and lack of awareness about the existence and importance of clinical trials (Clark et al., 2019). To encourage a more representative and diverse sample to willingly engage in this project about drug development processes, it is advantageous to make their participation justifiable. This is especially important to this project as it is seeking to reach those who have systematically experienced greater obstacles to health based on

[1] (https://data.bls.gov/cgi-bin/cpicalc.pl?cost1=75.00&year1=201012&year2=201703),

characteristics historically linked to discrimination or exclusion (e.g., race/ethnicity, socioeconomic status) (Warren et al., 2019). Therefore, a renumeration amount of $75 for a 90-minute individual interview is considered appropriate.

Incentives are often used to encourage participation in research. When applied in a reasonable manner, incentives are viewed as an acknowledgement of participation rather than an unjust inducement (Groth, 2010; Halpern, et al 2004). If the incentive is not adequate, participants may initially agree to participate and then fail to appear for the scheduled time, resulting in incomplete data collection and potential loss of government funds associated with recruitment costs and moderator time (Morgan & Scannell, 1998).

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] 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.

Type/Category of Respondent	**No. of Respondents**	**Participation Time (minutes)**	**Burden (hours)**
Adult Patients and Caregiver	20	90	30
Patient Advocate Representative	20	90	30
Totals	**40**		**60**

8. FEDERAL COST: **[**Provide an estimate of the annual cost to the Federal government.]

The estimated annual cost to the Federal government is 60 hours x $75 = $4,500

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?

[X] Yes [ ] 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?

We intend to recruit 15-20 patients and caregivers, and 15-20 patient organization representatives for a maximum total of 40 interviews.

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. Trained research staff based at the University of Maryland will organize and facilitate the individual interviews. Invitations to participate in individual interviews would be sent by email. Potential participants will be screened by the research staff. The interviewer will follow a structured interview guide. Up to 40 individual interviews will be scheduled.

The information gathered will be qualitative in nature, focusing on what patient and patient organization factors influence participation in FDA patient-engagement programs. Open-ended questions will allow us to gather more qualitative information to have a better understanding of patient and caregiver engagement and its heterogeneity in food allergy drug development.

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
    [ ] In-person
    [ ] Mail
    [X] Other, Explain

Interviews will be conducted by trained research staff based at the University of Maryland. Each session will include one member of the study team and one participant. Interviews will be audio and video recorded and transcribed.

Given the ongoing COVID-19 public health emergency, all data will be collected from participants via web-based interviews on Zoom.

Please find attached as appendices the following materials:

(a) Invitation emails to be sent to potential participants
(b) Interview guides
(c) Screeners
(d) Patient Flyer
(e) Consent form

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

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

REFERENCES:

Clark, L. T., Watkins, L., Piña, I. L., Elmer, M., Akinboboye, O., Gorham, M., Jamerson, B., McCullough, C., Pierre, C., Polis, A. B., Puckrein, G., & Regnante, J. M. (2019). Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. *Current Problems in Cardiology*, *44*(5), 148–172. https://doi.org/10.1016/j.cpcardiol.2018.11.002

Groth, S.W. (2010). Honorarium or coercion: use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*, *41*(1), 11.

Halpern, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(7), 801-803.

Morgan, D.L. & A.N. Scannell. (1998) *Planning Focus Groups*. Thousand Oaks, CA: Sage.

Warren, C. M., Turner, P. J., Chinthrajah, R. S., & Gupta, R. S. (2021). Advancing Food Allergy Through Epidemiology: Understanding and Addressing Disparities in Food Allergy Management and Outcomes. *The journal of allergy and clinical immunology. In practice*, *9*(1), 110–118. https://doi.org/10.1016/j.jaip.2020.09.064