FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS (0910-0360)

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

TITLE OF INFORMATION COLLECTION:

U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Database Customer Survey to Industry and External Stakeholders

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   On January 29, 2020, FDA unveiled a mobile-friendly, interactive, database of antiretroviral (ARV) drugs that provides product labeling and package label information for each drug product as well as updates on manufacturing sites, shelf-life, pediatric indications, and other critical information. The database benefits a wide variety of stakeholders and allows them to more efficiently gather, organize, and provide information related to FDA ARV drugs tentatively approved or approved under the PEPFAR program.

   The goal of this survey is to understand the current level of satisfaction with the database's services and information it provides. To obtain this understanding, we would like to survey industry members on their customer satisfaction and experience. We would also use this costumer survey to request customers recommendations on improving those services and information to make it more useful to them when using the database.

2. **Intended use of information:**

   The information gathered from this survey would help our working group identify areas of improvement for the database and confirm what areas of the database offer the greatest value to external stakeholders and customers. Customer feedback will help our database working group identify, prioritize, and sequence the improvements for the second phase of the project and inform our decision making moving forward.

3. **Description of respondents:**

   We would like to extend a standard survey to the following external ARV procurement organizations:

   - FHI360
   - Global Fund
   - Bill & Melinda Gates Foundation
   - Clinton Health Access Initiative
   - Ethiopian Pharmaceuticals Supply Agency (EPSA)
   - Kenya Medical Supply Agency (KEMSA)
   - Pan American Health Organization (PAHO)
   - United Nations Children's Fund (UNICEF)

- United Nations Development Programme (UNDP)
- Unitaid
- South African Department of Health

4. **Date(s) to be Conducted:**

   Between February and March 2022

5. **How the Information is being collected:**

   The data will be collected via Survey Monkey.

6. **Confidentiality of Respondents:**

   Responses will be collected anonymously, and any analysis of the results will be shared in aggregate. 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.

7. **Amount and justification for any proposed incentive:**

   No incentive will be offered.

8. **Questions of a Sensitive Nature (Data will be kept private to the extent allowed by the law):**

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

9. **Description of Statistical Methods:**

   This is a web-based survey data collection.

   BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Single users	75 respondents	10	14 hours

REQUESTED APPROVAL DATE: November 1, 2021

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