TITLE OF INFORMATION COLLECTION

FDA Customer Satisfaction Survey, User Fee OMB Control No. 0910-0360

DESCRIPTIONS OF THE SPECIFIC COLLECTIONS

1. **Statement of Need**

   The Food and Drug Administration (FDA), Office of Financial Management (OFM), Division of User Fees is requesting approval from the Office of Management and Budget of a generic clearance for online surveys that comply with Executive Order 12862, that requires federal agencies to "survey customers to determine the kind and quality or services that they want and their level of satisfaction with existing services."

   User Fees website is a portal for industry customers to create a coversheet that details the nature of application that industry customer would like to make to the FDA Center for various programs namely Animal Drug User Fee (ADUFA), Animal Generic Drug User Fee (AGDUFA), Prescription Drug User Fee (PDUFA), Medical Device User Fee (MDUFMA) and Medical Device User Fee (MDUFMA) – Registration & Listing. The URL of the portal is: https://userfees.fda.gov/OA_HTML/fdaCAcdLogin.jsp
   User Fee portal also provides information about various payment options that industry customer can use and a URL to connect to PAY.GOV for making payments using credit card / Debit card and Automated Clearing House (ACH)

2. **Intended Use of Information**

   Information gathered by this survey would be used as an input to Exhibit 300 per OMB guidelines. This survey will provide accurate data to meet the strategic goal of "Effective Management of Human Capital/Information Technology/Resources" per Exhibit 300. The measurement indicator per Exhibit 300 is "Percentage of customer satisfaction among industry user fee applicants as reported in annual surveys".

   In addition, the feedback we receive from industry customers will help us identify areas, where we can improve user fee portal experience and optimize our services to them.

3. **Description of Respondents**

   Respondents to the survey are basically industry customers or their affiliates or agents who come to User Fee website for submitting a coversheet describing in broad terms what they plan to submit to FDA Center. The User Fee Website allows industry customers to enter information relating to pre- and post-market submissions for Prescription Drugs, Medical Devices, Animal Drugs and Device facility & registration.

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

   User Fee system is an online system available 24*7 and accessed by industry customers around the world. Industry users would be entering the survey once

they create and submit coversheet(s). However the data analysis activity will be performed for each calendar year to determine customer satisfaction indicator and analyze ways to improve the user experience for a better customer service.

5. **How The Information is Being Collected**

   The survey will be posted online on User Fee iStore website. Once customer submits coversheet to FDA, the web page (or URL) to enter the survey would be displayed. The link will invite customers either to enter the survey and provide feedback about their experience with the user fee website or cancel out and close the session. There survey is optional. The respondents will complete the survey and submit it online.

6. **Confidentiality of Respondents**

   As part of this customer survey, no sensitive or personal information is collected from the respondents. The only information that is required is the name of the customer which is anyhow entered as customer comes to submit coversheet. Besides the information that would be collected is not part of any system of records or personally identifiable information and does not contain any demographic characteristics.

7. **Amount and Justification for any Proposed Incentives**

   The participation in the survey is completely voluntary and no payments or gifts will be provided to survey respondents.

8. **Questions of a Sensitive Nature**

   The information collected will not contain any sensitive information related to customers or customer contact that is entering in survey questionnaire. All the questions in the survey will relate to the ease of use of various functions provided to industry customers and that involves create a cover sheets, payment instructions for their application, whether it is for new prescription drug, or a medical device or animal generic drug or for registration & listing of the facility.

9. **Description of Statistical Methods**

   The information collected would be used to compute percentage of industry customers satisfied with their experience with the User Fee portal. There is no statistical sampling and no grouping of data is involved. This survey would essentially provide us number of customers who are conveying us areas of improvements.

10. **Burden of Information Collected:**

The total estimated burden is about 10 Hours per annual based on the estimate that about 300 customers would participate in the survey per year. These estimates are based on the feedback User Fee helpdesk currently receives, every year, regarding the ease of navigation and general feedback about the system.

Table 1—Estimated Annual Reporting Burden[1]

Type of survey	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Minutes per Response	Total Hours
Internet Survey	300	1	300	2	10
Total					**10**

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

iStore Survey Confidentiality Statement

The following disclosure statement will be used for the User Fee application online customer survey disclosure statement:

"Your Participation / nonparticipation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. All respondents, identification, and information are confidential and will be anonymous, unless otherwise indicated. In instance where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act"