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: Request for Surveys CDER Small Business and Industry Assistance (SBIA) soliciting feedback on conferences

1. PURPOSE:

The Food and Drug Administration Center for Drug Evaluation and Research (CDER) Small Business and Industry Assistance Program (SBIA) provides support and guidance to small pharmaceutical businesses that are seeking FDA approval to manufacture new drugs. CDER SBIA provides this support by hosting Webinars and in-person conferences, by making online courses available through CDER Learn, by providing information through the FDA Website and by responding to individual requests for information received by both email and phone. In order to better serve the small pharmaceutical business community, CDER SBIA needs data and information about both the changing needs of small pharmaceutical businesses seeking approvals from the FDA, and how well the current programs are fulfilling those needs. Data and information is needed to:

- identify regulatory information in demand
- identify preferred communication means of small pharmaceutical businesses
- improve the efficiency and effectiveness of outreach to small pharmaceutical firms
- ensure outreach efforts are achieving desired outcomes
- identify relevance of content provided at conferences
- identify topics for consideration at future conferences

2. DESCRIPTION OF RESPONDENTS:

The small business pharmaceutical community consists of companies that are typically 500 employees or less, which are developing new drugs that will require FDA review and approval. Companies are located throughout the world, with the vast majority located within the United States. Of note, SBIA's conferences are not limited to small pharma. In fact SBIA's educational products (conferences, webinars, etc.,) are available to all pharma.

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.
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: Brenda Stodart

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 [ ] 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: Respondents are from the private sector

No. of Respondents: 3750
Participation time for each respondent: 5 min per conference (0.42 hrs/yr for 5 conferences)

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**
Private Sector – Pharmaceutical Industry	3750	0.42hr/yr	1575hr
Totals	**3750**	**0.42hr/yr**	**1575hr**

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

The estimated annual cost to the Federal government is $0

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: Targeted respondents will be the conference attendees.

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?

All conference attendees will be considered respondents and will be given the opportunity to provide feedback via survey.

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

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

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