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 and Focus Groups in Support of FDA Programs for Small Pharmaceutical Businesses

1. PURPOSE:

The Food and Drug Administration Center for Drug Evaluation and Research (CDER) Small Business Assistance Program (SBAP) provides support and guidance to small pharmaceutical businesses that are seeking FDA approval to manufacture new drugs. CDER SBAP 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 SBAP 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

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. The FDA has compiled a list of approximately 1,250 small pharmaceutical businesses that have previously attended CDER SBAP Webinars or conferences, which will serve as the list of respondents.

3. TYPE OF COLLECTION**:** (Check onebox. 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: Qualitative Feedback

4. CERTIFICATION:

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 <u>substantially</u> informing <u>influential</u> 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<u>:   Brenda Stodart   </u>

5. PERSONALLY IDENTIFIABLE INFORMATION **(PII):**

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 PAYMENTS:

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: 2000
Participation Time: 2000

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 – Small Pharmaceutical Businesses	2,000	1 hour per year	2,000 hrs.
Totals	**2,000**	1 hour per year	**2,000 hrs.**

8. FEDERAL COST: The estimated annual cost to the Federal government is: <u>$0_____</u>

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:

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

Potential Universe of Respondents:
A complete list of Webinar and conference attendees is attached.
Sampling Plan: All 2000 will be included.

Administration of the Instrument:

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? [X] Yes [ ] No (for focus groups only)