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: State Medical Board Directors Follow-up Questions to the November 1, 2018 Training

1. PURPOSE:

   To help the Center for Drug Evaluation and Research (CDER), Office of the Chief Counsel (OCC), and the Division of Information Disclosure Policy (DIDP) develop the best procedure/protocol for information sharing with State Medical Boards, under 21 CFR 20.88.

2. DESCRIPTION OF RESPONDENTS:

   The targeted group are the State Medical Board Directors. DIDP provided them with a training on November 1, 2018 and we would like to get some feedback on if and how an agreement under 21 CFR 20.88 would work for them or if a different approach would be better.

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
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[X] Other: Email

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: Sara M. Ashton, Office of Regulatory Affairs, Sara.Ashton@fda.hhs.gov, 313-393-8180.

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.

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

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
State, local, or tribal governments	50	5 mins. (0.08)	~~4~~

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: 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?

The Federation of State Medical Boards (FSMB) provided DIDP with a contact list, including emails to reach out to the Medical Board Directors.

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 (Email to the directors)
   [ ] Telephone
   [ ] 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.

REQUESTED APPROVAL DATE: February, 2019.

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