

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Financial Reporting Focus Group

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

In the authorizations for FDA collection of user fees under the Prescription Drug User Fee Act VI (PDUFA), the Biosimilar User Fee Act II (BsUFA), and Generic Drug User Fee Act II (GDUFA), FDA committed to developing and publishing a five-year financial plan for each program, as well as to update the content and format of the annual financial reports for these programs. FDA is currently engaged in developing the template for the five-year plans and considering updates to the annual financial report templates. As part of this effort, we would like to get input from key external stakeholders on draft of these templates. This input would help to ensure that the final report templates support transparency and stakeholder understanding of the financial status of these programs.

2. Intended use of information:

The information collected would help inform the development of the plan and report templates and would help ensure these documents support transparency and stakeholder understanding of the financial status of these programs.

3. Description of respondents:

Respondents would be representatives from the industry trade associations that were party to the PDUFA, BsUFA, and/or GDUFA negotiations.

4. Date(s) to be conducted and location(s):

During the week of December 4, 2017 (actual time to be scheduled based on respondent availability).

5. How the Information is being collected:

The draft templates would be presented to the respondents. A series of discussion questions would be presented to help facilitate structured feedback. A contractor will organize and facilitate the session (s).

6. Number of focus groups:

One to two focus groups will be scheduled, depending on the availability of the respondents.

7. Amount and justification for any proposed incentive:

None

8. Questions of a Sensitive Nature:

None

- 9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):**
 Invitations would be sent via email to the relevant industry trade associations. They would select the individuals to represent their organization.

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)
Trade Association Representative	30	120	60

REQUESTED APPROVAL DATE: November, 2017

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FDA CENTER: Center for Drug Evaluation and Research