OMB Control Number 0910-0697 (Expires 12/31/2023)

Booz Allen Hamilton Small Group Discussion Outlook Invitation

- From: Booz Allen Hamilton (Booz Allen)
- To: Applicants, healthcare providers, patients, patient advocates, and other government agencies

Outlook Invitation Title: Independent evaluation of the implementation of the Benefit-Risk Framework – Request to participate in a small group discussion

[Good morning/Good afternoon [name]],

We are an independent consulting firm that has been contracted by FDA to conduct an evaluation of FDA's Benefit-Risk Framework. The Benefit-Risk Framework is FDA's framework to assess benefits and risks of new drugs and biologics and was developed to improve the consistency and clarity of benefit-risk assessment during the premarket review process. We are reaching out to request your participation in a small group discussion to gather insights on FDA's Benefit-Risk Framework's use in reviews of [therapeutic area] drugs and biologics. [Name & title at FDA] provided your name and contact information.

Background:
FDA committed to continuing the implementation of the Benefit-Risk Framework (BRF) into review documentation processes. As a part of this commitment, FDA contracted Booz Allen to conduct an independent evaluation to assess how the BRF is being applied by reviewers across FDA, as well as how external stakeholders, including applicants, healthcare providers, patients, patient advocates, and other government agencies, interact with the BRF as part of the drug and biologic review process.

Our goal is to create a report that capture insights into the BRF's clarity, understandability, and utility, as well as identify best practices and opportunities for improvement.

What participation will include:
Your participation in this discussion will require approximately 90 minutes of your time. We will first request that you review the BRF in section(s) within the FDA review memo. This should take no longer than 30 minutes. We will then request that you meet with us for 60 minutes to respond to questions will assessing the clarity, understandability, and utility of that BRF.

Attached are the following documents:

- The FDA review documentation for [*not necessarily presented as a list, but the following information will be provided:* application number, established name, indication], which can be found on FDA's website here: Drugs@FDA: FDA-Approved Drugs.
- Discussion guide for your reference

Please let us know if you are interested in participating in small group discussions. If so, we will follow-up to find a time that works best for your schedule.

If you have any questions or concerns, please contact the Booz Allen Project Manager, Kendra Orjada, at Orjada_Kendra@bah.com.

We thank you in advance for your time.

Sincerely,
[BAH name] (Booz Allen analyst)
[BAH email]