

Attachment A

Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

Invitation

OMB Control Number 0910-0883

Expiration Date: XX/XX/20XX

Paperwork Reduction Act Statement: The Paperwork Reduction Act of 1995 provides that an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0883. The time required to complete this information collection is estimated to average 5 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

The survey we are conducting is on behalf of the U.S. Food and Drug Administration (FDA).

Dear [Insert Outsourcing Facility Name (City, State)] team,

We hope this message finds you and your team well. As you may know, Deloitte Consulting LLP works with the FDA's Compounding Quality Center of Excellence (CoE) in their efforts to support outsourcing facilities to improve the quality of drugs they produce.

To inform the CoE's research this year, **FDA is inviting all registered outsourcing facilities to participate in a survey** to provide insights, perspectives, and inputs on relevant industry topics.

Please click here to take the survey.

The deadline to complete the survey is **11:59 PM EST [Month Day], 2025** and is estimated to take 15-30 minutes to complete. FDA requests **only one survey response per FDA registered outsourcing facility**. This considered, please coordinate with your team to incorporate perspectives from various roles within your facility. If your company has multiple registered outsourcing facility locations, you will receive a survey invitation email for each registered location as shown on the FDA Registered Outsourcing Facilities webpage.

Survey questions cover a range of topic areas such as outsourcing facility production, drivers of growth, challenges, future industry perspectives, CGMP and quality, experiences with Form 483s, and engagement with FDA Compounding Quality Center of Excellence resources.

The survey is being administered by Deloitte Consulting LLP as a third party and all responses to the survey will be **anonymous** and **non-attributable**. While FDA will utilize the information

obtained from survey responses, FDA will not have any direct involvement with administering the survey or collecting and tabulating the results.

We look forward to hearing from you and thank you in advance for your participation! For those of you who have taken this survey in the past, thank you for your continued participation that informs FDA actions to further the outsourcing facility industry.

Best,
Deloitte Consulting LLP, Compounding Quality Center of Excellence