United States Food and Drug Administration

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

OMB Control No. or 0910-NEW

SUPPORTING STATEMENT

Part B. Statistical Methods

1. Respondent Universe and Sampling Methods

The number of entities covered by this data collection is up 80 registered outsourcing facilities with up to 300 respondents. The number of entities covered by this data collection will include all outsourcing facilities registered with FDA at the time the survey is administered.

The registered outsourcing facilities are known entities and contacts who work with the FDA and are registered in the FDA system. They have expressed interest in engaging with the FDA already to support the research, including through the survey, to inform FDA's future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement of the industry. As such, we are confident that the response rate will be in line with OMB expectations.

2. Procedures for the Collection of Information

Survey participants from all registered compounding outsourcing facilities will be engaged. The contact lists maintained by the FDA for registered compounding outsource facilities include email addresses and phone numbers for the target survey participants, which will be used to reach out to participants to invite them to participate in the electronic survey.

Survey responses will be collected in the electronic survey tool. Survey responses will be anonymous and non-attributable. The results of the survey will be aggregated and not associated with any individual person.

3. Methods to Maximize Response Rates and Deal with Non-response

FDA has engaged and maintains contact with the target survey participants, who have expressed interest in providing their input through the survey. Given the expressed interest of the target survey participants in participating in the survey, there is confidence that the response rate will meet OMB expectations.

To maximize response rates and address non-response, follow-up procedures will be applied repeatedly to engage targeted survey participants through various communication channels. Repeat direct emails ~2-3 weeks apart (up to 3) will be sent to remind target participants of the

dates that the survey is open and of the importance of providing their input to inform FDA's future engagement with compounding outsourcing facilities.

4. Test of Procedures or Methods to be Undertaken

Only "fine tuning" changes to the survey are expected as a result of pretesting and a combined approval for the pretest and main survey are requested.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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