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OUTSOURCING FACILITIES ASSOCIATION

January 23, 2026

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments on Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

Dear FDA,

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA registered outsourcing facilities ("503Bs") operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). OFA's members provide compounding services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications. OFA has been actively following U.S. Food and Drug Administration's (the "FDA") implementation of the Compounding Quality Act ("CQA") and has brought together members of industry to advocate for a reasonable and practical rollout of the CQA.

OFA appreciates FDA's interest in comments from those engaged in the practice of pharmacy compounding specific to burdens from registration of outsourcing facilities and reporting of drugs, the submission of adverse event reports, and activities associated with States entering into memoranda of understanding with the Secretary. We offer the following comments to your 4 proposed questions:

1. Necessity and Practical Utility of the Proposed Collection

OFA agrees that FDA's collection of certain information is necessary for the effective performance of its public health mission. However, OFA requests increased transparency from the FDA regarding its processes for managing the adverse events reported to the agency. Specifically, OFA requests further information and clarity from FDA regarding:

- How the reported adverse event information is used within FDA for monitoring.
- Whether identified patients or clinics are contacted by FDA and what criteria does the FDA use to determine if the reports call for contact from FDA.
- Whether reported information is communicated externally for any purpose and if so, what are those purposes.

- Whether information is reported to state regulatory entities or other federal regulatory entities.

We encourage FDA to continue modifying its practices and sharing information based on feedback from regulated entities.

2. Accuracy of FDA's Burden Estimates and Underlying Methodology

We appreciate the effort FDA has made to estimate respondent burden; however, we encourage FDA to revisit several underlying assumptions. In our experience, the time required for respondents may be higher than estimated due to:

- Significant difficulty and time spent following up with contacting clinics or patients to answer the follow up questions received from the FDA.
- The above is especially true for non-serious events.

We recommend FDA increase its transparency as discussed above regarding its methodology for certain follow up requests regarding adverse event reports.

3. Enhancing the Quality, Utility, and Clarity of the Information Collected

To improve the quality and clarity of the data FDA receives, OFA recommends:

- Increased transparency regarding FDA's use and dissemination of data collected.
- Increased transparency regarding FDA's triggers for follow on information requests.
- Increased transparency regarding FDA's contact with patients or clinics in response to data submissions.

OFA believes increased transparency from FDA will ease the burden of data collection and increase quality and clarity of data collected because the regulated entities will have a better understanding of the use of the data, which may eliminate certain needs for additional internal review prior to submission.

Further, regarding quality utility and clarity of information collected, OFA wishes to renew its comments on the questions asked by FDA as stated in our October 31, 2024 comment to Docket No. FDA-2024-N-3762. OFA proposes the following additional questions to better inform FDA's research:

1. What percentage of your operations are compounding from bulk versus compounding from finished dosage form?
2. What are the research and development costs associated with a 503B preparing to produce a compounded drug product?
3. If a drug is removed from the Drug Shortage List, how long should outsourcing facilities be able to sell existing inventory?

4. How much does it cost to perform the testing required under cGMP?
5. If a drug is added to the Drug Shortage List, how long does it take until you can fulfill orders using bulk drug substances to compound the product?
6. What challenges do you face when compounding from FDA approved product as a starting material?
7. What supply issues have you experienced?
8. Where do you source starting materials from?
9. How has FDA guidance affected the operation of your outsourcing facility?
10. How can FDA help to explain to customers that outsourcing facilities follow CGMP, the same standards that pharmaceutical manufacturers follow?
11. How can FDA publicly identify outsourcing facilities that are compliant with regulations from those that are non-compliant?
12. How can FDA increase transparency with inspections?
13. What is your experience with the development of the 503B Bulk List?
14. How can FDA improve the development of the 503B Bulk List?
15. What issues have you experienced with State Agencies?
16. What percentage of your operations are compounding sterile products versus nonsterile products?
17. What provisions of Section 503B affect patient safety?
18. What topics could the industry benefit from additional FDA guidance?
19. What factors do outsourcing facilities consider when determining whether, or not, to help alleviate shortages by compounding a drug that is added to the Drug Shortage List?
20. Would it be helpful to outsourcing facilities if the FDA provided advanced notice that it was considering removing a drug from the Drug Shortage List?
21. Would you be willing to provide information on the volume of drugs that are on the Drug Shortage List that you are compounding in order for the FDA to get better information on the true size of the market for that drug considering that such information may become publicly available?

4. Minimizing Burden on Respondents

As discussed above, increased transparency from FDA, while asking additional questions as proposed above, will minimize burden on respondents and increase the quality and utility of information collected. Further, increased transparency by FDA through the proactive publication of 483s issued to drug manufacturers registered under section 510 of the FD&C Act similar to the proactive publication and transparency provided for 503B outsourcing facilities would minimize information asymmetry and burdens for outsourcing facilities and the American public.

Conclusion

We appreciate FDA's commitment to transparent and efficient information collection practices and welcome the opportunity to contribute to this process. We stand ready to provide any

additional information that may be helpful as FDA finalizes the proposed collection and processes.

Respectfully submitted,

/s/ Lee H. Rosebush

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