Medisca
PARTNERS IN WELLNESS

Address 661 Route 3, Unit C,
Plattsburgh, NY, 12901 USA
Toll Free 1-800-932-1039
Fax 855-850-5855
www medisca.com

November 1, 2024

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration
Dockets Management Staff (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted via www.regulations.gov

RE: Comment to Docket No. FDA–2024–N–3762: Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

Dear Ms. Roth,

Medisca Inc. ("Medisca" or "the Company") thanks the Food and Drug Administration ("FDA" or "the Agency") for issuing an opportunity for public comment on the Agency's proposed collection of information pertaining to compounding outsourcing facilities operating under §503B of the Food, Drug and Cosmetic Act (FD&C Act). Medisca submits this comment to the above-referenced docket for your consideration.

We appreciate FDA's interest in expanding its understanding of the challenges and opportunities faced by §503B compounding outsourcing facilities and commend the Agency for its commitment to improve "the quality of compounded human prescription drugs to promote patient safety."[1] This important solicitation of public input will help ensure the agency receives valuable information, insights, and recommendations to ensure that the planned survey achieves the Agency's goal of deepening its "understanding of the outsourcing facility sector and increase [its] efficacy in developing a Center of Excellence that is responsive to outsourcing facilities' needs."[2] Please know Medisca stands ready to work with the Agency to achieve this important public health goal.

[1] 89 *Federal Register* 72411 (Sept. 5, 2024)
[2] Id. at 72412

1. About Medisca.

Founded in 1989, Medisca is a global leader in the procurement, repackaging, and distribution of pharmaceutical ingredients and technology with a vast portfolio of over 2,000 products completed by a library of more than 10,000 customized medication formulas, expertise and services in pharmaceutical compounding, continuing health care education, analytical testing, and more. Headquartered in Montreal, Quebec with over 10 locations throughout Canada, United States, Australia, and Germany, Medisca serves diverse healthcare and wellness sectors across the globe, including pharmacies, outsourcing facilities, hospitals and clinics, laboratory and research, contract manufacturers, and wholesale, among others.

2. General Comment.

Under §503B of the FD&C Act, compounding outsourcing facilities play an essential role in supplying much-needed medications to hospitals, health systems, and other healthcare facilities across the country. Outsourcing facilities also help strengthen American manufacturing of critical medications. By soliciting input from – and engaging directly with – registered outsourcing facilities and related human prescription drug compounding stakeholders, the Agency is illustrating its commitment to working collaboratively with compounding outsourcing facilities and is recognizing the critical role that compounding outsourcing facilities play in our nation's healthcare system. Specifically, we support FDA undertaking "in depth research to better understand outsourcing facilities' challenges and opportunities in different areas to help guide decisions regarding future training and other engagement."[3] This effort and the specific survey research enumerated in the *Federal Register* notice will help strengthen the FDA's Compounding Quality Center of Excellence, which in turn will help advance patient safety.

3. Proposed Survey Questions

We appreciate FDA's interest in ensuring that the survey questions capture the most important information from compounding outsourcing facilities and that the survey not place an undue burden on respondents. It is essential to strike a balance between comprehensiveness of research and ensuring that a survey not be so time and resource intensive that the response rate is low and/or responses are incomplete. Generally, we believe that the agency has struck such a balance in the proposed number and nature of the questions listed in the *Federal Register* notice.

[3] Id. at 72411.

A critical area that we strongly urge the agency to explore more in-depth via the survey pertains to the opportunities and challenges for compounding outsourcing facilities with respect to responding to drug shortages. When the FDA determines that the supply of a drug cannot meet demand, outsourcing facilities can respond to the patient need and compound a copy of the FDA-approved drug. As you know, shortages can result from myriad causes, including but not limited to: natural disasters like the recent hurricanes in the U.S. southeast[4]; market demand far outpacing manufacturing capacity; supply-chain challenges; and contamination during manufacturing. Unfortunately, shortages are increasingly common and, therefore, it is essential they be addressed in the survey.

Specifically, we believe it would be beneficial to the Agency to better understand the barriers, challenges, and opportunities that outsourcing facilities face in both the lead up to prepare copies of shortage drugs and the "wind-down" process, as well as the impact on the outsourcing facility when a drug is removed from the shortage list. To this end, we urge the Agency to add questions to the survey that specifically address the lead up and wind down processes of making copies of shortage drugs. Below are sample/suggested questions to include:

- What financial and operational considerations inform an outsourcing facility's decision to copy a drug on the shortage list?
- What financial and operational considerations exist for an outsourcing facility that had been making a copy of a drug on the shortage list and it is later removed?
- What resources or assistance do outsourcing facilities need in procuring the individual components/raw materials to a formulation they intend to manufacture?

Medisca recognizes that the Agency seeks to solicit information while not overly burdening the respondent to supply that information. We believe adding these questions will only marginally increase the time needed to complete the survey and should not increase the burden of time to complete the survey to greater than one hour. Moreover, we believe respondents would be eager to provide information related to drug shortages. Furthermore, the information gathered will help address a critical health need around access to medications, impact of drug shortages, and how the role of compounding outsourcing facilities during drug shortages can be strengthened.

[4] US Food and Drug Administration. October 15, 2024. Hurricane Helene: Baxter's manufacturing recovery in North Carolina. https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina

4. Conclusion

Again, we commend FDA for soliciting input from the public regarding the research questions that will be asked of employees at compounding outsourcing facilities and related human prescription drug compounding businesses. The information that will be collected via the survey should help inform balanced solutions and the development of communications, education, and training to ensure that compounding outsourcing facilities can continue to play a critical role within the healthcare system to mitigate the negative impact of drug shortages whether they are caused by manufacturing issues, supply-chain bottlenecks, or a natural disaster.

As a leading supplier to compounding outsourcing facilities, Medisca welcomes the opportunity to partner with FDA. Together, we can assist in addressing and maintaining patient access to required medications with patient health and safety at the forefront. This is made possible through our vendor qualification programs, vast network and resources for the ongoing procurement of components in support of safe and quality compounded medications. Should you have any questions or if we can be of any assistance, please contact our Washington, D.C. federal policy representative, Shalini Vallabhan, Senior Policy Advisor at Venable (scvallabhan@venable.com).

Sincerely,

Sanjay Goorachurn
CEO Medisca