Submitted electronically to: www.regulations.gov

June 17, 2024

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

Re: Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act [Docket No. FDA–2023–N–0061]

Dear Dockets Management Staff:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA on its *Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies also provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Overview of the Rule

FDA has issued a proposed rule to establish criteria for two lists of drug products or categories of drug products that present demonstrable difficulties for compounding (Demonstrable Difficulties for Compounding Lists or DDC Lists) under certain sections of the Federal Food, Drug, and Cosmetic Act. Drug products or categories of drug products that appear on the DDC Lists cannot qualify for certain statutory exemptions, and therefore may not be compounded under, either section 503A or section 503B, respectively. FDA is also proposing to establish criteria for evaluating drug products or categories of products for inclusion on one or both lists. For evaluating drug products or categories of drug products for inclusion on the DDC Lists, FDA is proposing to establish the following criteria: the formulation complexity, drug delivery mechanism complexity, dosage form complexity, complexity of achieving or assessing bioavailability, compounding process complexity, and complexity of physicochemical or

analytical testing of the drug product or category of drug products. Additionally, FDA is proposing to identify the first three categories of drug products on both DDC Lists: (1) oral solid modified-release drug products that employ coated systems (MRCs), (2) liposome drug products (LDPs), and (3) drug products produced using hot melt extrusion (HMEs).

NCPA opposes this proposed rule, and stresses that FDA should not finalize it, for the following reasons:

Insufficient Notice and Comment Period for this Proposed Rule

NCPA does not believe that stakeholders have a sufficient notice and comment period for this proposed rule, as FDA is seeking to finalize both criteria for creating the drug products for inclusion on the DDC Lists, as well as the actual categories to include on the DDC lists.

Demonstrable Difficult to Compound Lists Lack Known Substantiating Evidence

NCPA also notes that while FDA is planning to add items to the 503A and 503B DDC lists, FDA does not show any evidence that either 503As or 503Bs are making these compounds. FDA admits this lack of evidence:

> Because we find no evidence of marketing of the three categories of human drug products that we propose to include on the DDC lists, compounders would not incur costs to discontinue marketing any existing products that the proposed rule would identify as demonstrably difficult to compound under sections 503A or 503B. However, interested compounders would incur small costs to read and understand this proposed rule.[1]

FDA Should Preserve Right to Compound in the Future

In its proposed rule, FDA acknowledges that the agency is unaware of any human drug compounders using any of these technologies currently. Therefore, there is no risk to public health or safety and finalizing this rule is unnecessary. Further, as technology advances production of these dosage forms may become feasible, and FDA has provided no mechanism to reverse any decisions made by implementation of this rule. Thus, FDA seeks to unnecessarily and unfairly restrict pharmaceutical innovation in the compounding sector.

FDA Does Not Have Statutory Authority to Add "Categories" to the 503A DDC List

FDA's proposed rule seeks to add categories of drug products to the 503A DDC list and 503B DDC list. Statutory language in Section 503B permits FDA to add categories to the 503B DDC list with the language "[…]**drugs or categories of drugs** that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness

[1] "Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis." *FDA.* Available at: https://www.fda.gov/media/176946/download?attachment.

of the drug or category of drugs, taking into account the risks and benefits to patients,[…]**[NCPA emphasis].**"[2]

However, statutory language in the Section 503A states "such drug product is not a drug product identified by the Secretary by regulation **as a drug product** that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product;[…]**[NCPA emphasis]**."[3] The omission of "categories" from the statutory language means that FDA is not allowed to add the 3 categories of products to the 503A DDC list. **Therefore, FDA must not add the three proposed categories to the 503A DDC list.**

DDC Criteria #6: Analytical Testing Complexity is not an Appropriate Criteria for a Compounded Drug or Category of Drug

FDA has identified six criteria it proposes to consider in determining whether drug products or categories of drug products present demonstrable difficulties for compounding under sections 503A and 503B of the FD&C Act, the sixth of which is "Physicochemical or analytical testing complexity." However, compounders do not conduct analytical testing on their own products. Rather, compounders use third party analytical labs, and the experts in those specialty labs and processes are responsible for the analytics. Just as the labs are not qualified to make compounds, compounders are generally not qualified to test compounds. Therefore, the complexity of testing is irrelevant to compounders provided the lab has the expertise. Examples of complex testing provided in the proposed rule include cell-based assays and mass spectrometry, both of which are commonly used in testing of compounded drugs for the past two decades.

Conclusion

NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

[2] See Compounding Quality Act, Section 503(B)(a)(6)(A), available at: https://www.fda.gov/drugs/human-drug-compounding/text-compounding-quality-act.

[3] See Federal Food, Drug, and Cosmetic Act, Section 503(A)(b)(3)(A), available at: https://www.fda.gov/drugs/human-drug-compounding/section-503a-federal-food-drug-and-cosmetic-act.