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Alliance for Pharmacy Compounding

October 20, 2023

Gail Bormel, JD, RPh
Director, Office of Compounding Quality and Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Recent addition of substances to Category 2 – Documentation request

Dear Dr. Bormel:

On behalf of the Alliance for Pharmacy Compounding, I write to request additional information regarding FDA's recent updating of the list of bulk drug substances nominated for use under section 503A. In particular, our interest is in the process that led to the addition of substances to the respective lists and in learning more about the safety risks the agency says it has identified related to substances added to Category 2.

As you know, APC is the voice for pharmacy compounding, representing more than 600 compounding small businesses across America – including 4,300 compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

The FDA's statement indicates that substances were added to Category 2 "because FDA has identified significant safety risks with [those] substances." However, the agency statement did not indicate the process FDA followed to determine those risks or what those risks were.

We request that the agency share publicly, as soon as practicable:

1. A brief explanation of the process it followed in assessing risks of the nominated – and subsequently added to Category 2 – substances; and
2. A summary of the safety risks identified with each substance recently added to Category 2.

Explanation of both the process and the substance of FDA's concerns about specific items will be helpful in better understanding the agency's thinking about those substances. One of our concerns is that some of the recently added substances will remain available via non-pharmacy vendors selling research-grade substances of unknown provenance directly to patients. Therefore, an unintended effect of the addition of certain substances to Category 2 may be to drive patients to obtain riskier versions of what purports to be one of the substances in question – an outcome counter to what the agency seems to be aiming to achieve via its recent action.

More importantly, more detail about FDA's substance-specific safety concerns can assist APC and other groups in educating pharmacists, technicians, and other stakeholders about why the substances were added to Category 2 and the risks the agency sees as inherent in compounding with them.

Thank you for considering this request for additional information. If you have questions about our request, please contact me at scott@a4pc.org or 404.844.8607.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer