June 6, 2022

Sarah Taylor, PharmD
Academy Director

Regulatory Update – June 8, 2022 Meeting of the Pharmacy Compounding Advisory Committee (PCAC)

What is the Pharmacy Compounding Advisory Committee?

The Pharmacy Compounding Advisory Committee (PCAC) provides advice to the Food and Drug Administration (FDA) regarding scientific, technical, and medical issues that pertain to sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

What is the significance of the upcoming PCAC meeting?1

Currently, pharmacies operating under section 503A of the FD&C Act may only compound with a bulk drug substance if it meets one of the following three requirements[JHMI1] :

1. Comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;
2. Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or

3. Appear on FDA's list of bulk drug substances that can be used in compounding (the 503A bulks list) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

PCAC hosts meetings periodically during which bulk drug substances are evaluated for potential inclusion on the FDA's 503A Bulk Substances List (i.e., the "positive list"). The upcoming PCAC meeting, scheduled to occur on June 8, 2022, will evaluate glutathione, ferric subsulfate, enclomiphene citrate, and ammonium tetrathiomolybdate.2 Currently, the FDA is proposing that all four of these bulk drug substances NOT be included on the positive list.3

How is Fagron working to support the interests of compounding pharmacists?

Fagron and Letco have filed a detailed comment to PCAC in support of continued use of glutathione in compounding. We are also working with other organizations to assist in the development of a unified approach, including both written comments and oral presentations, to PCAC.

What can be done to make your opinion known?

Comments may be submitted to the docket at this link: https://www.regulations.gov/document/FDA-2021-N-0357-2586. Comments must be submitted on or before June 7, 2022. The meeting broadcast details may be found at 2022 Meeting Materials, Pharmacy Compounding Advisory Committee | FDA.

Sources:

1. Bulk Drug Substances Used in Compounding Under Section 503A of the FD&C Act. US Food and Drug Administration. Bulk Drug Substances Used in Compounding Under Section 503A of the FD&C Act | FDA. Updated 2/20/2020. Accessed 5/20/22
2. https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-8-2022-meeting-pharmacy-compounding-advisory-committee-meeting-announcement-06082022
3. https://www.fda.gov/media/158541/download
4. https://www.regulations.gov/document/FDA-2021-N-0357-2586.

For further information or questions, please feel free to reach out to us by heading to www.fagronacademy.us!