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December 26, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4205–P
P.O. Box 8013
Baltimore, MD 21244

Re: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability. [Docket No. FDA–2015–D–3517]

Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA on its *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*; Draft Guidance for Industry.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies 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. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Scope of Interim Guidance

FDA is developing this list of bulk drug substances (the 503A bulks list), and this guidance describes FDA's interim regulatory policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for licensed physicians that compound human drug products using bulk drug substances while the list is being developed. FDA is issuing this interim guidance stating that, until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product and that is not the subject of an applicable USP or NF monograph, provided that the following conditions are met:

- The bulk drug substance appears in 503A Category 1 on FDA's website at https://www.fda.gov/media/94155/download. A Category 1 substance may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for FDA to evaluate it and has not been identified by FDA as a substance that presents a significant safety risk in compounding prior to the publication of a final rule;
- The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i) of the FD&C Act);
- The bulk drug substance is accompanied by a valid COA; and
- The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FD&C Act.

Exclusions

FDA also stated that drug products compounded using a bulk drug substance that does not meet each of the above conditions are not within the scope of the policy described in this guidance. For example, drug products compounded from the following bulk drug substances are not within the scope of the policy:

- Substances not nominated for the 503A bulks list or that were nominated on or after the date this guidance is finalized;
- Substances that are the subject of a final rule concluding that they will be included, or not included, on the 503A bulks list; and
- Substances that are the subject of an applicable USP or NF monograph or a component of an FDA-approved drug.

NCPA supports this policy as it preserves patient access to compounds that have not yet been evaluated for inclusion or exclusion to the 503A bulks list. However, as FDA does not intend to categorize bulk drug substances that the public nominates for inclusion on the 503A bulks list on or after the date this guidance is finalized, NCPA asks that FDA maintain transparency of the revision of the 503A bulks list. We recommend that FDA publish on some cadence, say once a quarter, substances that are nominated and currently evaluated for inclusion on the 503A bulks list, with opportunity for comment. Public view and input into the nomination process is critical for patients and for the compounding pharmacists that serve them.

NCPA appreciates the opportunity to share with FDA our comments and suggestions on the *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*; Draft Guidance for Industry. 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