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April 27, 2021

Frances Gail Bormel, JD, RPh
Acting Director, Office of Compounding Quality and Compliance
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Sent via email: Frances.Bormel@hhs.fda.gov

Re: Request to Delay Enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act

Dear Ms Bormel:

The National Association of Boards of Pharmacy® (NABP®) writes to respectfully request that Food and Drug Administration (FDA) delay enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act until October 2022. Section 503A(b)(3)(B)(ii) reads:

SEC. 503A. PHARMACY COMPOUNDING.

(b) Compounded Drug.--

(3) Drug product.--A drug product may be compounded under subsection (a) only if--

(B) such drug product is compounded in a State--

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330]

As you know, NABP, founded in 1904, represents the pharmacy regulatory and licensing authorities in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, The Bahamas, and all 10 Canadian provinces. NABP's mission is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

In recent weeks, NABP has received comments from multiple member boards of pharmacy that the timeline is too short for them to take the action needed to sign the MOU by October 2021 and have asked about FDA delaying enforcement.

The majority of boards cite the burden that the coronavirus disease 2019 (COVID-19) pandemic has placed on them, causing a backlog in most, if not all, board activities and resulting in the need for boards to prioritize COVID-19-related actions above everything else.

Some boards also cite issues beyond those related to COVID-19. Several states have indicated that regulatory changes, which involve lengthy processes and require extensive public comment periods, are needed. Others have indicated that statutory amendments are necessary, and the legislatures are placing a great deal of focus on COVID-19-related legislation. In addition, states where legislatures only meet biennially, eg, Montana, Nevada, North Dakota, Texas, may not have appropriate changes in place until 2022 or even 2023.

Additionally, the potential lack of access for patients who rely on pharmacies that are located in states that cannot sign the MOU is of great concern to NABP and its member boards. **In fact, at least one state has no in-state compounding pharmacies and its patients rely exclusively on interstate shipment for their needed medications.** As a result, an October 2021 enforcement date may cause an interruption in therapy for these and other patients nationwide.

To summarize, NABP anticipates that an enforcement delay will give many states the time needed to take the necessary actions to sign the MOU. As you know, NABP is strongly supportive of the work that FDA has done to protect patients from high-risk compounders and would like as many states as possible to join in this effort. Association staff is hard at work developing the Information Sharing Network and will soon be onboarding several states that have decided to sign the MOU. NABP is pleased that patients in these states will soon benefit from the work put into this effort.

Thank you for your attention to this matter. NABP hopes that FDA will consider this request.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

A handwritten signature in black ink, appearing to read 'Al Carter', with a stylized flourish extending to the right.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

cc: NABP Executive Committee