

September 26, 2019

In 2013, the Drug Quality and Security Act (DQSA) was enacted that created a new section of the Food, Drug, and Cosmetic Act (FD&C), 503B, which created a category of compounders, referred to as outsourcing facilities. One requirement of outsourcing facilities is that they can only compound using a bulk drug substance if it appears on a list approved by the Food and Drug Administration (FDA) as demonstrating a clinical need, the 503B Bulks List. The FDA solicited nominations from the public and have a list of approximately 200 substances that are being considered for inclusion.

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the FDA, is conducting research to better understand how compounded drugs containing these nominated bulk drug substances are used in clinical practice. As a medical expert, we appreciate your input, and the input of your colleagues, regarding the use of these substances in your clinical practice. This information will be used by the FDA to inform its development of the 503B Bulks List.

We have identified 7 substances that appear to have a clinical use in oral medicine. Through completion of the survey below, we aim to identify how you use each of these substances in your practice. The survey has questions specific to the substances you select. The table below outlines the substances that are included on the survey. All responses are anonymous.

Substances
Alpha lipoic acid
Boric acid
Coenzyme Q10
Dyclonine
Iodoform
Malic acid
Scopolamine

We hope you will provide us your valuable insight by completing the survey. To access the survey please click the link provided below.

Survey 1: https://umaryland.az1.qualtrics.com/jfe/form/SV_2sZH1RRVoJPN3SJ

For any questions about the survey or for more information about this project please visit:
<http://www.pharmacy.umaryland.edu/research/compounding/> or contact Ashlee Mattingly, PharmD,
BCPS at compounding@rx.umaryland.edu.

Sincerely,

A handwritten signature in black ink that reads "Ashlee Mattingly". The signature is written in a cursive style with a large initial "A" and a long, sweeping underline.

Ashlee Mattingly, PharmD, BCPS
Assistant Professor