



NATIONAL CONSUMERS LEAGUE

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June 5, 2017

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Gottlieb:

On behalf of American consumers who depend on your agency to ensure the safety and integrity of their food and medicines, we strongly urge you to continue to advance the FDA's compounding guidance, *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, that was released in December 2016.

Bipartisan Congressional action was taken following the deaths of 60 people and the sickening of hundreds of others in 2012, which stemmed from unsanitary practices at a compounding pharmacy in New England. The increased oversight, federal inspection authority, reasonable restrictions on compounding before prescriptions are written and other components of the increased regulation as outlined in the FDA's guidance are directly to the benefit of the safety and security of American consumers.

We appreciate the FDA's past leadership on this issue and respectfully request that the December 2016 guidance, as issued, continue to be the policy implemented by the agency.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sally Greenberg', is written in a cursive style.

Sally Greenberg
Executive Director