Division of Dockets Management (HFA‑305)

Food and Drug Administration

Department of Health and Human Services

5630 Fishers Lane   Rm. 1061 Rockville, MD 20852

Re:  Docket FDA-2015-D-4750 The ‘‘Deemed to be a License’’ Provision of the BPCI Act: Questions and Answers; Draft Guidance for Industry; Availability; Request for Comments on Preliminary List of Affected Applications For related information”

Dear Sir or Madam,

I would like to thank the FDA for the opportunity to submit comments to this docket. I am a (insert type of therapy) patient and I am deeply concerned about the possible loss of access for compounding, to certain drugs that appear on the “Preliminary List of Approved NDAs for Biological Products That Will Be Deemed to be BLAs on March 23, 2020.”

It has recently come to my attention that the Drug Quality Security Act may not have provided an exemption for compounding with drug products approved under section 351 of the Public Health Service Act, and that the Biologics Price Competition and Innovation Act would deem certain products approved under section 505 as biological products. I would like to request the FDA to clarify if this will affect access to my compounded medications.

I have been utilizing compounded medications that use one or more of the drug substances that appear on the “Preliminary List.” I have successfully used these medications for \_\_\_\_\_\_ years without issue. I require compounded medications because\_\_\_\_\_\_\_\_\_. Restricting access to my compounded medications could cause delays or failures in my therapy.

Again, thank you for the opportunity to publicly comment on this process.

Sincerely,

***Instructions for Commenting to FDA on Deemed to Licensed Biological Products***

Below is the link to the FDA Docket # [FDA-2015-D-4750](https://www.regulations.gov/comment?D=FDA-2015-D-4750-0021)

# The ‘‘Deemed to be a License’’ Provision of the Biologics Price Competition and Innovation Act: Questions and Answers; Draft Guidance for Industry; Availability; Request for Comments on Preliminary List of Affected Applications For related information”

To comment:

1. Click on the link below.

2. A window will open prompting the comment and contact information. Copy and paste your comment into the Comment Field or upload as a document. If you choose to upload documents, it is best to upload them as PDF files.

You can choose to make the comment anonymously if desired.

Link to FDA Docket:

[Enter Docket FDA-2015-D-4750-0021](https://www.regulations.gov/comment?D=FDA-2015-D-4750-0021)