



APC MEETING REQUEST: FDA CDER/CBER OCTOBER 5, 2022

A brief statement of the purpose of the meeting and a list of the specific objectives/outcomes expected from the meeting

We wish to meet with representatives of CDER and CBER to discuss the substance of a September 16, 2022, letter from a CDER Branch Chief to NABP's CEO regarding compounding with desiccated thyroid extract. We're caught off guard by the stance the agency has taken in deeming DTE a biologic, and we have several serious concerns about both the substance of the letter and the process CDER seems to be taking in deeming DTE a biologic.

Objectives:

1. To sustain patient access to DTE therapy – including commercially available and compounded preparations, as needed.
2. To brief the agency on potentially grave impacts on patients resulting from the reclassification of DTE as a biologic.
3. To raise concerns about the path the agency has taken – a letter to a trade association, as opposed to any formal action or communication – in deeming DTE a biologic.
4. To point out concerns about the rationale for deeming DTE a biologic.
5. To inquire about impacts of the agency's action on commercially available Thyroid USP, none of which to our understanding is not covered by a BLA.
6. To inquire of the agency about seeming inconsistencies in reporting of supposed DTE adverse events in FDA's FAERS database.

• Proposed agenda that includes an estimated time

PROPOSED AGENDA:

1. Introductions
2. Agency path in deeming DTE a biologic
3. Basis of agency rationale for deeming DTE a biologic
4. Agency process to deem DTE a biologic
5. Impacts of agency action on commercially available Thyroid USP
6. Potential patient impacts resulting from reclassification of DTE as a biologic
7. Inconsistencies in FDA's FAERS database regarding DTE adverse events

We anticipate an hour-long discussion.

- **Draft list of questions to facilitate the discussion**

What is the problem the agency is trying to address via this reclassification of DTE as a biologic?

Can the agency share perspective on deeming DTE as biologic, since it is not listed in the Purple Book, and the substance being pointed to is not listed as the active ingredient of the product?

What is the agency's rationale for stating the reclass in a letter to a trade association rather than an official and public agency action and/or communication to the compounding industry, particularly to chemical wholesalers who register thyroid USP powder with FDA?

Are there currently sponsors seeking a BLA for thyroid USP tablets to maintain patient access to this medication?

Does the agency intend to deem other chemicals which are not listed as active ingredients in certain substances as biologics?

Has the agency considered the additional implications of other products being converted to biologics due to the use of the definition of a protein in this manner?

What is the agency's understanding of the impacts of this reclassification of DTE on patients?

- **A list of all individuals (including titles) who will attend the meeting from your organization, including any consultants**

Dave Miller, RPh, PhD, FAPC, FACA, owner, Keystone Pharmacy, Grand Rapids, Michigan and President, Alliance for Pharmacy Compounding

Michelle Moser, PharmD, owner, Maker's Pharmacy, Mt. Vernon, Washington, and Board Member, Alliance for Pharmacy Compounding

Matt Martin, PharmD, BCSCP, Director of Clinical Services, PCCA, and member, Alliance for Pharmacy Compounding

Scott Brunner, CAE, Chief Executive Officer, Alliance for Pharmacy Compounding

David Pore, JD, Hance Scarborough Law Firm, public policy consultant, Alliance for Pharmacy Compounding

- **A list of FDA employees you would prefer attend the meeting:**

At a minimum, we request that OCQC Director Gail Bormel, OCQC's Gabrielle Cosel, and representatives of CBER participate in the meeting.

- **Suggested dates and times (i.e., morning or afternoon) for the meeting, as well as any dates that cannot be accommodated.**

We request that we meet ASAP. The following dates are unavailable:

October 10
October 11
October 25
October 26
October 27
October 28
October 31

- **APC Contact: Scott Brunner | scott@a4pc.org | 404.844.8607**