OMB/OIRA/HHS/FDA Call:

Meeting Date/Time:	09/19/2023 03:30 PM
Requestor's Organization:	American Pharmacists Association
Requestor's Client:	Compounding Core Group
Email:	mbaxter@aphanet.org
Phone:	202-459-8963
RIN:	0910-AI31
Rule Title:	Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act

Summary:

- Thank you for the opportunity for the American Pharmacists Association's views regarding FDA's Proposed rule related to Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act.
- According to the summary in the Spring 2023 unified agenda, this proposed rule contains two issues:
    - First, FDA is proposing to establish the criteria by which it would evaluate drug products and categories of drug products for inclusion on the list of drug products and categories of drug products that present demonstrable difficulties for compounding under section 503A and/or under section 503B.
    - Second, based on the results of its evaluation of nominated categories of drug products to date, as well as consultation with the Pharmacy Compounding Advisory Committee (PCAC), FDA is also proposing to include certain categories of drug products on these lists.
- Our reason for meeting with you today is to raise procedural concerns.
- In 2015, FDA's Pharmacy compounding advisory committee held a meeting to discuss the criteria for inclusion on the demonstrably difficult list.
- We are not aware of FDA providing a notice and comment period for these criteria to date.
- We strongly believe that the criteria should be published as a proposed rule to give an opportunity for public notice and discussed, and THEN, once the criteria are finalized, that should be the basis for consideration by FDA for the demonstrable difficult-to-compound list.

- If the criteria change during the rulemaking process, then stakeholders may not be able to comment appropriately on the drug products and categories if it is a single step proposed rule.
- You can’t build the plane and fly it at the same time.
- We urge you to consider this procedural issue as you review the notice of proposed rulemaking and the proposed rule.
- Thank you.