Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock

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Purpose of Public Meeting

- Provide stakeholders with an opportunity to present to FDA their perspectives concerning access to office stock from outsourcing facilities in light of FDA's enforcement policies as proposed in the revised draft guidance on current good manufacturing practice (CGMP) for human drug compounding outsourcing facilities.

Agenda

9:00 AM – 9:45 PM	**Introductory remarks and background**
9:45 AM – 10:00 PM	*Break*
10:00 PM – 11:30 PM	**Provider perspectives and discussion**
11:30 PM – 12:30 PM	*Lunch*
12:30 PM – 2:00 PM	**Outsourcing facility and supplier perspectives and discussion**

Proposed Discussion Topics

Perspectives related to demand and supply of office stock, including:

- Ways in which HCPs seek to identify outsourcing facilities that compound the drugs they want for office stock, as well as issues, if any, with this process.
- Communications between HCPs and outsourcing facilities to address potential issues related to requested formulations, timing, and order size.
- Coordination or consolidation of orders among providers for same or similar compounded drug products.
- HCPs' experiences with the availability of office stock products from outsourcing facilities.

Proposed Discussion Topics

- **Perspectives related to orders for drug products that an outsourcing facility has not made or does not routinely make, including:**
  - Factors outsourcing facilities consider before deciding whether to fill an order for a requested compounded drug product that it has not previously made or does not routinely make.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities filling orders for requested products not previously or routinely made.

Proposed Discussion Topics

- **Perspectives related to small volume orders of office stock products, including:**
  - HCPs' experiences seeking small volume orders from outsourcing facilities.
  - Factors outsourcing facilities consider before determining whether to produce small batches of compounded drug products for office stock.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities' decisions regarding filling small volume orders and/or producing small batches of compounded drug products for office stock.
  - Whether/how the revisions proposed in the revised draft guidance would affect registration of compounders engaged in smaller-scale production as outsourcing facilities.

Proposed Discussion Topics

- **Perspectives related to beyond use dating for office stock products, including:**
  - How long HCPs seek to keep office stock drug products before use.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities' production of compounded drug products for office stock with beyond use dating desired by HCPs.