Compounding Quality Center of Excellence Annual Conference

Stakeholder Feedback and FDA Policy Development

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Overview

- Importance of stakeholder feedback to FDA's policy development process
- Ways FDA may receive stakeholder input
- Examples of stakeholder input informing policy development

Importance of Stakeholder Feedback (1 of 2)

Importance of Stakeholder Feedback (2 of 2)

- Ensures that when FDA develops policy the Agency has current and relevant information from stakeholders on
  - current practices,
  - how FDA policies affect their practice, and
  - barriers/opportunities they perceive in relation to regulation now and in the future.
- Ensures FDA has opportunities to ask clarifying questions of stakeholders and also provide clarifications to stakeholders about current public policy, to ensure optimal shared understanding
- Transparency regarding stakeholder feedback (e.g., during notice and comment process) allows stakeholders to learn from each-other as well, and understand the information FDA is aware of

Ways FDA Obtains Stakeholder Input

Ways FDA may Receive Stakeholder Input

- Comment processes for guidances, rules, and *Federal Register* notices for bulk drug substances
- Open docket on drug compounding
- Stakeholder listening sessions
- Stakeholder inquiries
- Meetings with state regulators
- COE engagement activities, including the COE survey
- And others

Examples of Stakeholder Input Informing Policy Change

Examples of Stakeholder Input Informing Policy Development

- Hospital and Health Systems Guidance
- Oxitriptan Guidance
- SPL and NDC database updates
- Beta Lactam Guidance
- Ibuprofen Oral Suspension Guidance
- Wholesaling Guidance

Hospital and Health Systems Guidance (1 of 2)

- Draft Guidance: Hospital and Health System Compounding Under the FD&C Act, published in 2016.
- Proposed policy provided that FDA does not intend to take action if a hospital pharmacy distributes compounded drug products without first receiving a patient-specific prescription or order as long as certain conditions were met, including:
  - Compounded drug products are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are **located within a 1-mile radius** of the compounding pharmacy

Hospital and Health Systems Guidance (2 of 2)

- FDA received feedback from stakeholders on the “1 mile radius” proposed policy, including concerns with the workability of this circumstance for hospitals and health systems
- FDA published a revised draft guidance in 2021, Hospital and Health System Compounding Under Section 503A of the FD&C Act
- Proposed policy provides that FDA does not intend to take action if a hospital pharmacy distributes compounded drug products without first receiving a patient-specific prescription order (including a chart order) as long as certain conditions are met, including:
  - The compounded drug products are used or discarded **within 24 hours of transfer out of the pharmacy**

Oxitriptan Guidance

- **Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency**; Immediately in Effect Guidance for Industry (published July 2019)
- FDA developed this guidance in response to communications from pharmacists and caregivers regarding the use of oxitriptan to treat patients with BH4 deficiency following issuance of the February 19, 2019, final rule, which placed oxitriptan on the list of bulk drug substances that cannot be used to compound drug products under section 503A of the FD&C Act.
- According to those communications and other information available to the Agency, oxitriptan is the standard of care for the treatment of BH4 deficiency, which is caused by several different rare enzyme defects that result from gene mutations.

Note: FDA did not consider BH4 deficiency during its initial review of this substance for the 503A Bulks List. Thus, this guidance addresses the conditions under which FDA does not intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician for the use of bulk oxitriptan to compound oral drug products for the treatment of identified individual patients with BH4 deficiency provided certain conditions are met.

SPL and NDC Database Updates

- FDA received requests to:
  - Create a new marketing category for outsourcing facility compounded drugs within the product reporting system
  - Include compounded drug NDCs in the NDC Directory
- FDA created marketing category:
  - “Outsourcing Facility Compounded Human Drug Product (Exempt from Approval Requirements)”
- FDA published a new feature in the NDC Directory Search
  - Search tool now includes “Compounded Products” (Outsourcing Facility Compounded Human Drug Products)

Beta Lactam Guidance

- During acute shortages of amoxicillin oral antibiotic powder for suspension, FDA received stakeholder requests for clarification about preparation of compounded versions of those products from FDA-approved tablets and capsules.
- FDA published guidance on compounding certain Beta-Lactam Products in Shortage Under Section 503A of the FD&C Act.
- Guidance document implemented immediately because of the public health need for amoxicillin oral antibiotic suspension products (though remains subject to comment).

Ibuprofen Oral Suspensions Guidance

- FDA received reports related to:
  - increased demand for pediatric fever-reducing medications, including ibuprofen oral suspension products.
  - Hospitals, health systems, and State-licensed pharmacies experiencing challenges with obtaining these medications to use for fever and pain treatment of pediatric patients as well as for adults who are unable to swallow solid oral dosage forms
- FDA published immediately in effect guidance to provide temporary flexibility to help ensure that treatment options are available.
- The guidance describes FDA's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities
  - for use in hospitals and health systems, and
  - for provision to state-licensed pharmacies and applicable federal facilities to dispense to patients for home use, following receipt of a valid, patient-specific prescription from a health care provider.

Wholesaling Guidance

- In June 2023 FDA published draft guidance on Prohibition on Wholesaling Under Section 503B of the FD&C Act.
- Prior to publication, FDA received numerous stakeholder requests for Agency clarification on its interpretation of this provision, including statutory text that provides that the prohibition on wholesaling "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)."
- In the draft guidance FDA interprets this provision to mean that a drug compounded by an outsourcing facility may be eligible for the exemptions in section 503B of the FD&C Act where the drug is distributed directly from an outsourcing facility to a health care facility, such as a hospital or clinic, where the drug is administered to a patient, or to a State-licensed pharmacy or Federal facility where the drug is dispensed pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act.

Questions?