

Section 804 Importation Program (SIP) Informal Meetings

March 3, 2026

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Executive Order

- Lowering Drug Prices by Once Again Putting Americans First issued on April 15, 2025
- **Sec. 10 . *Increasing Prescription Drug Importation to Lower Prices.*** Within 90 days of the date of this order, the Secretary, through the Commissioner of Food and Drugs, shall take steps to **streamline and improve** the Importation Program under section 804 of the Federal Food, Drug, and Cosmetic Act to **make it easier** for States to obtain approval **without sacrificing safety or quality.**

Purpose of Informal Meetings



Promotes **EFFICIENT** feedback and engagement with FDA 804 staff



Provides preliminary informal feedback from FDA to facilitate communication regarding program requirements



Offers states and tribes the opportunity to submit documentation for preliminary feedback prior to formal submission



Fosters open dialogue to assist in the development of proposals



Serves as informational sessions that do not result in final agency actions or opinions

What is an Informal Meeting?



Formal

- Executive level participation
- Takes longer to schedule
- Requires a formal agenda and may result in formal meeting minutes
- Will require questions submitted in advance
- More complex topics
- Requested and/or scheduled through FDA's Intergovernmental Affairs Office

Informal

- Staff level participation
- Statements non-binding on either party
- Quick to schedule
- May not require an agenda, formal documentation, or meeting minutes
- May facilitate fluid discussion and open dialogue
- Can be a better venue for less complex topics
- May request prior to submission of formal documents
- Requested directly to the program mailbox

Meeting Examples

- Informal feedback on program requirements for states developing or planning to develop a new SIP
- Clarification regarding regulations or operations of the importation program
- Pre-submission requests:
 - New or revised (after expiration) SIP
 - Pre-import requests
- In-process clarifications on requirements or operations for an active SIP
- Notifications of potential delays
- Urgent requests

Informal Meeting Considerations



An email request may be appropriate to ask certain questions (e.g., questions requiring written response, administrative questions)



A request for an informal meeting may result in a formal meeting if more appropriate

Similarly, a formal meeting request may result in an informal meeting



If a formal meeting was previously held on a particular topic, it may be best to continue formal discussion surrounding that topic



States and Tribes should provide as much information as possible to ensure a productive meeting

How to Request an Informal Meeting

These informational meetings are optional and are only available to states and tribes as potential SIP sponsors

States and tribes may also request meetings with FDA after SIP submission

As appropriate, please include a general overview of the topics proposed for discussion and materials for FDA's review in the request

Email:

SIPDrugImportsandRFP@fda.hhs.gov

to request an informal meeting