Marketing Status Reports

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Learning Objectives

- Provide an overview of the types of marketing status reports
- Provide an overview of the Federal Food, Drug, and Cosmetic (FD&C) Act's section 506I reporting requirement
- Explain key aspects of the section 506 I reporting process

Statutory and Regulatory Background

- **Annual Report**
  - 21 CFR 314.81(b)(2)(ii)(a)
- **506C Reporting** (Drug shortage advance notification)
  - The FDA Safety and Innovation Act (FDASIA) of 2012
  - Section 506C of the FD&C Act (21 U.S.C. 356c; see also 21 CFR 314.81(b)(3)(iii) (iv))
- **506I Reporting** (additional requirement)
  - The FDA Reauthorization Act (FDARA) of 2017
  - Section 506I of the FD&C Act, (21 U.S.C. 356i)

Annual Report

- Within ***60 days*** of the anniversary date of U.S. approval of the application
- Quantity of the drug product distributed
  - Distributors
  - National Drug Code (NDC) number
  - Total number of dosage units of each strength or potency
    - Domestic use
    - Foreign use

506 C Reporting

- Permanent discontinuances and temporary interruptions that may lead to a shortage
  - ***At least 6 months*** prior to the date of the discontinuance or interruption of manufacturing, or asap
  - Critical drugs
  - API for certain drugs
  - Biological products
- Public non-compliance letter

506 C Reporting

- How to notify FDA
  - drugshortages@fda.hhs.gov
  - CDER Direct NextGen Portal at https://edm.fda.gov/wps/portal/
  - CBERshortage@fda.hhs.gov
- Other reporting requirements are not substitutable for 506C reporting

506 I Reporting

- ***Notification of withdrawal from sale*** —180 days prior to withdrawing an approved drug from sale
- ***Notification of drug not available for sale*** —Not available for sale within 180 days of the date of approval

506 I Reporting

- Section 506I(e) requires FDA to update the Orange Book based on the information provided in application holder's reports
- Section 506I(d) authorizes FDA to move products to the discontinued section of the Orange Book
  - If applicant fails to submit any of these marketing status notifications

Challenge Question #1

Who is required to report marketing status of their drug products to the FDA?

A. All NDA and ANDA holders are required to report marketing status of their drug products to the FDA

B. Only NDA and ANDA holders of certain critical drugs are required to report marketing status of their drug products to the FDA

C. Only NDA and ANDA holders of certain non-critical drugs are required to report marketing status of their drug products to the FDA

D. NDA and ANDA holders are not required to report marketing status of their drug products to the FDA

“Withdrawal From Sale”

- Permanent withdrawal of a product
- Ceases its own distribution (not due to a routine, temporary interruption in supply), even if the application holder plans to eventually return to the market

“Withdrawal From Sale” Notification

1. The National Drug Code(s) (NDCs) under which the drug is listed (21 CFR part 207)
2. The established name of the drug
3. The proprietary name of the drug, if applicable
4. The NDA or ANDA number
5. The strength of the drug
6. The date on which the drug is expected to no longer be available for sale
7. The reason for the withdrawal

“Withdrawal From Sale” Notification

- A notification for products marketed under multiple NDCs should only be submitted if the applicant holder has ceased marketing under all relevant NDCs
- All NDCs being discontinued should be listed in the notification
- Notification for a product marketed as both a branded drug product and authorized generic should only be submitted when both will cease marketing

“Withdrawal From Sale” Notification

- Date the drug is expected to no longer be available for sale
  - Use actual date
  - ***Cease*** its own distribution

“Withdrawal From Sale” Notification

- Submit through the electronic submission gateway
- Identify the submission as an “**ADMINISTRATIVE CHANGE/NOT AVAILABLE FOR SALE**”
- Submit a copy to CDERCollections@fda.hhs.gov for NDAs only

Not Available for Sale

- Drug product has not being marketed
  - within 180 days of the date of approval

“Not Available for Sale” Notification

1. The established name of the drug
2. The proprietary name of the drug, if applicable
3. The NDA or ANDA number
4. The strength of the drug
5. The date on which the drug will be available for sale, if known
6. The reason for not marketing the drug after approval

“Not Available for Sale” Notification

- Potential reason for not marketing
  - Lack of demand
  - License agreement
  - Interruption in the supply of drug product components
  - Issues related to production for a commercial launch at day 180

“Not Available for Sale” Notification

- Submit through the electronic submission gateway
- Identify the submission as an “**ADMINISTRATIVE CHANGE/NOT AVAILABLE FOR SALE**”
- Submit a copy to CDERCollections@fda.hhs.gov for NDAs only
- Include the anticipated start date of manufacturing and distribution
  - Use actual date

Return a Product to market

- First, determine whether the submission of a supplement is required prior to or at the time of introduction of the drug product into the marketplace
- Notify the Orange Book 30-60 days before the anticipated launch date or prior to the approval of a relevant PAS
  - Use actual date
- Submit through the electronic submission gateway
  - Identify the submission as an "**ADMINISTRATIVE CHANGE /NOTIFICATION OF COMMERCIAL MARKETING"**
  - **Clearly indicate in your cover letter if a supplement approval is needed prior to the start of distribution**

Challenge Question #2

The Orange Book staff will initiate moving your products to the discontinued section according to

A. Cease distribution date

B. Expiry date of your last lot

C. Submission date of your notification

D. 30-60 days after the submission date of your notification

Resources

- Electronic Orange Book
- Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act, Guidance for Industry
- Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format, Guidance for Industry
- Orange Book Question and Answer, Draft Guidance for Industry

Summary

- Different requirements for market status reporting
  - Annual Report, 506C, 506I
- Review the Final Guidance Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format, Guidance for Industry

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Orangebook@fda.hhs.gov


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