Regulatory Reminders to the Finish Line

CAPT Vince Sansone PharmD
CDR Rinku Patel PharmD, BCPS
Office of Generic Drugs
CDER | US FDA

Generic Drug Forum 2024 – April 11, 2024

Learning Objectives

- Discuss how and when to respond to changes to patent information
- Review best practices for ANDA applicants
- Bring it all together

What Industry is Doing Well

- Certifying to all listed patents
- Providing timely notice……generally
- Submitting documentation of notice for original PIV certifications
- Notifying FDA of filing of first civil action complaint

Areas for Improvement

- Addressing timely submitted later listed use codes
  - If addressing with a PIV certification, new certification is required
    - Submitting documentation of notice
- Addressing new listed exclusivities
  - Clearly state intent

Areas for Improvement

- Vigilance with respect to tracking 30-month stay dates
- Court decisions which impact when your ANDA is eligible for action
  - Notify FDA of the entry of all final court orders or judgments within 14 days pursuant to 314.107(e)
  - Orders must be signed

Areas for Improvement

- Commercial Marketing Notifications
  - Notify FDA within 30 days of pursuant to 314.107(c)(2)
    - Includes marketing of an authorized generic

You Control Your Destiny

MONITORING IS PARAMOUNT

Challenge Question #1

Within how many days are you required to submit notification of court actions or consent to approval?

A. 60 days

B. 30 days

C. 14 days

D. 10 days

Challenge Question #2

Which of the following statements is NOT true?

A. I can be eligible for final approval before the 30 month stay expires without having to submit a court action

B. A court order does not need to be signed by the judge

C. There is no set requirement to submit documentation of notice

D. My original PIV certification will cover a newly listed use codes

E. All of the above

Questions?

Regulatory Project Manager

Patent and Exclusivity Mailbox

CDER-OGDPET@fda.hhs.gov