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Association for Accessible Medicines

Biosimilars Council
A Division of the Association for Accessible Medicines

GRx+Biosims

Successfully Managing Priority Generic Submissions

September 6, 2018

Engineering the Future
of Generic + Biosimilar Medicines

Session Description

As part of FDARA and GDUFA II, FDA has provided drug manufacturers a formal pathway for the development of priority generic drugs in order to meet needs of patients and caregivers in a timely manner

As manufacturers decide on strategies to develop priority generic products they will need to understand what the current FDA expectations mean to their development program, including the submission of pre- submission facility correspondences (PFCs)

This session will offer perspectives of what is important to consider when deciding to utilize the priority pathway for the development of generic products

Panel

- **Bob Iser,** VP, PAREXEL® Consulting (Moderator)
- **Kiran Krishnan**, SVP, Regulatory Affairs, Apotex
- **Scott D. Tomsky**, VP, Regulatory Affairs, Teva, North America
- **Aloka Srinivasan**, VP, Regulatory Practice, Lachman Consulting Services

What is a Priority ANDA

- FDA intends to consider an ANDA to be a *priority* ANDA if it meets the criteria listed in either section 505(j)(11)(A) of the FD&C Act, or the Center for Drug Evaluation and Research's (CDER's) Manual of Policies and Procedures (MAPP) 5240.3, *Prioritization of the Review of Original ANDAs, Amendments, and Supplements* (Prioritization MAPP).

Potential Priority Products

- Submissions with Patent certifications pursuant to 21 CFR 314.94(a)(12)
  - Generics with less than three ANDAs approved for the reference drugs with no blocking patents or exclusivities
  - Submissions with Paragraph IV certification that become eligible for approval during the review period
  - Submissions with Paragraph IV certification that have “first filer” status
- Submissions related to drug shortages
- PEPFAR products
- Products that address public health emergencies, government purchasing programs and other statutory mandates

Priority Review Goals Under GDUFA…

Table for Section I(A)(1) and (2): Original ANDAs

Submission Type	Goal
Standard Original ANDAs	90% within 10 months of submission date.
Priority Original ANDAs	90% within 8 months of submission date if applicant meets requirements under I(A)(2)(a).
	90% within 10 months of submission date if applicant does not meet requirements as described under I(A)(2)(b).

Table for Section I(A)(3) – (5): ANDA Amendments

Submission Type	Goal
Standard Major ANDA Amendments	90% within 8 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
Priority Major ANDA Amendments	90% within 6 months of submission date if preapproval inspection not required.
	90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(A)(4)(b).
	90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(A)(4)(c).
Standard and Priority Minor ANDA Amendments	90% within 3 months of submission date.

Priority Review Goals Under GDUFA…

Table for Section I(B)(1) and (2): PASs

Submission Type	Goal
Standard PASs	90% within 6 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
Priority PASs	90% within 4 months of submission date if preapproval inspection not required.
	90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(B)(2)(b).
	90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(B)(2)(c)

Competitive Generic Therapy (CGT)

FDARA Section 803, lays out the process for designation as a “competitive generic therapy.”

A drug is eligible for CGT designation if FDA determines that there is “inadequate generic competition.”

Potential Benefits – meetings and advice throughout development, experienced assessment team and cross disciplinary leadership, exclusivity…

Pre-Submission Facility Correspondence (PFC)

- **A PFC is required for a priority ANDA**

- A PFC is intended to provide FDA ***information needed to assess the facilities*** involved in manufacturing processes and testing of the drug, including facilities in corresponding Type II active pharmaceutical ingredient drug master files referenced in the application, and sites or organizations involved in bioequivalence and clinical studies used to support the application to determine ***whether an inspection is necessary***

Pre-Submission Facility Correspondence (PFC)

- **Revised PFC Draft Guidance – issued Nov., 2017**
  - Content and format of PFC (CTD sections)
  - Timeframes for pre-submitting sections of the ANDA containing *complete, accurate facility information (NLT 60 days prior to submission of ANDA)*
  - Possible outcomes of the Agency's assessment of pre-submitted ANDA
  - When and how the Agency notifies an applicant about the status

Discussion Questions

1. In the first year of GDUFA II, what lessons have been learned about the priority ANDA process and expectations?

2. What's important to consider when submitting PFCs for originals and amendments for priority ANDA products?

3. What should a company consider when deciding to submit a priority ANDA?

In the first year of GDUFA II, what lessons have been learned about the priority ANDA process and expectations?

What's important to consider when submitting PFCs for originals and amendments for priority ANDA products?

What should a company consider when deciding to submit a priority ANDA?

Questions?

THANK YOU

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