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Anatomy of a Priority Review

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Robert Pollock, M.S., R.Ph., Senior Advisor, Outside Director to the Board Lachman Consultants Services, Inc.

Kurt R. Karst, Director, Hyman, Phelps & McNamara, P.C.

Scott D. Tomsky, V.P. Regulatory Affairs, Teva, North America

Disclaimer

- This presentation contains a summary of the opinion and perspective from industry representatives on the topic of “Anatomy of a Priority Review”.

- This presentation does not necessarily represent the opinion of the presenters nor their employers.

Priority and Expedited ANDA Review: An Overview

Priority Review

- Priority Review under GDUFA Reauthorization
- Priority Review under FDARA
- Expedited Review under MAPP 5240.3

Priority Review Under GDUFA…

- Priority – means submissions affirmatively identified as eligible for expedited review pursuant to CDER's Manual of Policy and Procedures (MAPP) 5240.3, Prioritization of the Review of Original ANDAs, Amendments and Supplements, as revised (the CDER Prioritization MAPP).

Priority Review 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 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)

Priority Review Under GDUFA…PFC

- PFC Draft Guidance – issued June 2017
- Comment Period Closed September 18, 2017
- 8 comments submitted
- Revised Draft Guidance
  - Released November 3rd, 2017!

Priority Review Under FDARA…Section 801

- Amends FDC Act 505(j) to require FDA to prioritize the review of, and act within 8 months of the date of the submission of, an original ANDA submitted for a drug--

  "(i) for which there are not more than 3 approved drug products and for which there are no blocking patents and exclusivities; or"

  "(ii) that has been included on the Drug shortage list

Priority Review Under FDARA…Section 803

- Lays out the process for designation as a “competitive generic therapy.”
- A drug is eligible for designation as a competitive generic therapy if FDA determines that there is “inadequate generic competition.”
  - There is not more than one approved drug listed in the Orange Book (excluding discontinued section) that is the RLD, or “a generic drug with the same RLD as the drug for which designation as a competitive generic therapy is sought.”

Priority Review Under FDARA...Section 803

- **Designation benefits:**

  (1) Hold meetings with the applicant and the review team throughout the development of the drug prior to submission of the ANDA.

  (2) Provide timely advice to, and interactive communication with, the applicant regarding the development of the drug to ensure that the development of the drug to ensure efficient drug development.

  (3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of a CGT designated ANDA.

  (4) Assign a cross-disciplinary project lead

    (A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

    (B) to serve as a scientific liaison between the review team and the applicant.

Priority Review Under FDARA…Section 803

- **Designation benefits (continued):**
  180-day exclusivity period for CGT's—

  (I) if the application is for a drug that is the same as a CGT for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by any first approved applicant.

  (II) Limitation. The exclusivity period (I) shall not apply with respect to a CGT that has previously received an exclusivity.

Expedited Review Under MaPP5240.3

- For purposes of this MAPP, “expedited review” means that a submission will receive **heightened review priority** as determined by the OGD Division of Project Management staff (including the RPM) and OGD management.
- Expedited review may be granted following a request from the applicant (including where expedited review is requested for a supplemental ANDA, or at OGD’s initiative).

Priority and Expedited ANDA Review: Case Studies

Priority/Expedited Review

- **Priority Review under GDUFA II**
  - https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf
- **Priority Review under 2017 FDARA**
  - Section 801 (Priority Review of Generic Drugs) – FDC Act 505(j)(11)
  - Section 803 (Competitive Generic Therapies) – FDC Act 506H
    - https://www.congress.gov/115/bills/hr2430/BILLS-115hr2430enr.pdf
- **Expedited Review under MAPP 5240.3**
  - https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf)

The Case of PRETENT INHALIZER (notrealatol inhalation powder)

- Identified on FDA's List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic
  - https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf

- Identified on FDA's Drug Shortage List

The Case of PRETENT INHALIZER (notrealatol inhalation powder)

- ANDA applicant submits application to FDA on December 10, 2017.
- ANDA applicant certifies “No Relevant Patents”
- ANDA applicant submitted Pre-Submission Facility Correspondence to FDA on October 9, 2017.
- ANDA applicant requests Competitive Generic Therapy Designation on December 10, 2017.

What Priority Review Mechanisms Apply?

- **Priority Review under GDUFA II**
- **Priority Review under 2017 FDARA**
  - Section 801 (Priority Review of Generic Drugs) – FDC Act 505(j)(11)
  - Section 803 (Competitive Generic Therapies) – FDC Act 506H
- **Expedited Review under MAPP 5240.3**

Priority Review under GDUFA II?

Priority Review under 2017 FDARA Section 801?

Priority Review under 2017 FDARA Section 803?

Expedited Review under MAPP 5240.3?

The Case of FRIENDCHIP (smilealot)

- Listed in the Orange Book with no unexpired patent and non-patent exclusivities.
- Drug not identified on FDA's Drug Shortage List.
- FRIENDCHIP is listed in the "discontinued" section of the Orange Book, which section also identifies 2 approved, but not currently marketed, ANDAs. The "active" section of the Orange Book includes 1 ANDA for a generic version of FRIENDCHIP.

The Case of FRIENDCHIP (smilealot)

- ANDA applicant submits application to FDA on December 10, 2017.
- ANDA applicant certifies “No Relevant Patents”
- ANDA applicant submitted Pre-Submission Facility Correspondence to FDA on October 10, 2017.
- ANDA applicant requests Competitive Generic Therapy Designation on December 1, 2017.

What Priority Review Mechanisms Apply?

- **Priority Review under GDUFA II**
- **Priority Review under 2017 FDARA**
  - Section 801 (Priority Review of Generic Drugs) – FDC Act 505(j)(11)
  - Section 803 (Competitive Generic Therapies) – FDC Act 506H
- **Expedited Review under MAPP 5240.3**

Priority Review under GDUFA II?

Priority Review under 2017 FDARA Section 801?

Priority Review under 2017 FDARA Section 803?

Expedited Review under MAPP 5240.3?

The Case of FANTOM (motnaf)

- Listed in the Orange Book with U.S. Patent No. 999,999,999 expiring on December 11, 2018, and no unexpired non-patent exclusivities.

- Drug not identified on FDA's Drug Shortage List.

- FANTOM is listed in the "active" section of the Orange Book as a sole-source drug product; however, the "discontinued" section of the Orange Book identifies 3 approved, but not currently marketed, ANDAs.

The Case of FANTOM (motnaf)

- ANDA applicant submits application to FDA on December 12, 2017.
- ANDA applicant certifies Paragraph III to the ‘999 patent.
- ANDA applicant submitted Pre-Submission Facility Correspondence to FDA on October 13, 2017.
- ANDA applicant requests Competitive Generic Therapy Designation on December 15, 2017.

What Priority Review Mechanisms Apply?

- **Priority Review under GDUFA II**
- **Priority Review under 2017 FDARA**
  - Section 801 (Priority Review of Generic Drugs) – FDC Act 505(j)(11)
  - Section 803 (Competitive Generic Therapies) – FDC Act 506H
- **Expedited Review under MAPP 5240.3**

Priority Review under GDUFA II?

Priority Review under 2017 FDARA Section 801?

Priority Review under 2017 FDARA Section 803?

Expedited Review under MAPP 5240.3?

THANK YOU!!
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