Legal Issues in GDUFA, FDARA, and Administration Proposals

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
kkarst@hpm.com
September 2018

Agenda

- **Priority and Expedited ANDA Review**
- **Competitive Generic Therapies**
- **Trump Administration's 180-Day Exclusivity Proposal**

Priority and Expedited Review

Priority/Expedited 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 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**

Expedited Review Under MaPP 5240.3

- **Expedited Review**
  - **FDA will strive to act on an ANDA as soon as possible, including prior to the goal date if possible. An expedited review, though, does not result in a shorter goal date.**

- **Priority Review**
  - **FDA will either (1) give a shorter goal date or (2) grant an expedited review.**

Expedited Review Under MaPP 5240.3

- **Shorter Goal Date**
  - **In accordance with the GDUFA II Commitment Letter, FDA commits to one of the following (1) for original ANDAs, an 8-month goal date; (2) for major amendments, a 6- or 8-month goal date; or (3) for prior approval supplements, a 4- or 8-month goal date.**

II

Competitive Generic Therapies – Obtaining Designation and 180-Day Exclusivity

FDARA Section 803 (FDC Act 506H)

- Lays out the process for designation as a “competitive generic therapy.”
- Request must be made “concurrently with, or at any time prior to” ANDA submission.
- A drug is eligible for designation as a competitive generic therapy if FDA determines that there is “inadequate generic competition.”

FDARA Section 803 (FDC Act 506H)

- **“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.”**

FDARA Section 803 (FDC Act 506H)

- **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.**

FDARA Section 803 (FDC Act 506H)

- (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.

FDARA Section 808 (FDC Act 505(j))

- **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.**

FDARA Section 808 (FDC Act 505(j))

- **180-day exclusivity period for CGT's—**
  - **(II) Limitation. The exclusivity period (I) shall not apply with respect to a CGT that has previously received an exclusivity period.**

FDARA Section 808 (FDC Act 505(j))

- **The term "competitive generic therapy" means a drug—**
  - **(AA) that is designated as a competitive generic therapy under section 506H; and**
  - **(BB) for which there are no unexpired patents or exclusivities [listed in the Orange Book] at the time of submission."**

FDARA Section 808 (FDC Act 505(j))

- **The term "first approved applicant" means any applicant that has submitted an application that—**
  - **(AA) is for a CGT that is approved on the first day on which any application for such competitive generic therapy is approved;**
  - **(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the CGT; and**

FDARA Section 808 (FDC Act 505(j))

- **(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).**

FDARA Section 808 (FDC Act 505(j))

- **Special forfeiture rule for competitive generic therapy.**
  - **“The 180-day exclusivity period described in paragraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.”**

III

Trump Administration's 180-Day Exclusivity Proposal

Fiscal Year 2019 Budget Proposal

- **On February 12, 2018, the Trump Administration released a proposed Fiscal Year 2019 Budget.**

- **Tucked into the Proposed Budget are provisions concerning 180-day generic drug exclusivity that are billed as a way to increase generic drug competition.**

Fiscal Year 2019 Budget Proposal

- **“The proposal ensures that first-to-file generic applicants who have been awarded a 180-day exclusivity period do not unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period. Under this proposal, when a first-to-file generic application is not yet approved due to deficiencies, FDA would be able to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock, rather than waiting an indefinite period for the first-to-file applicant to fix the deficiencies in its application.”**

Fiscal Year 2019 Budget Proposal

- **In short, the concern the Trump Administration appears to want to address is a first applicant's ability to "park" 180-day exclusivity eligibility because of alleged "deficiencies" (e.g., unresolved current Good Manufacturing Practice ["cGMP"] concerns) that prevent FDA from granting final ANDA approval and commercial marketing under that application (thus triggering 180-day exclusivity) while subsequent ANDA applicants otherwise ready for approval are blocked from obtaining final approval solely because of a first applicant's continuing eligibility for exclusivity.**

Is New Statutory Authority Necessary?

- **The proposal is not necessary. FDA already has sufficient statutory and regulatory authority to determine that a first applicant has forfeited eligibility for 180-day exclusivity because of ANDA "deficiencies" preventing final approval.**
  - **FDC Act § 505(j)(5)(D)(i)(II) ("The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).")**

Is New Statutory Authority Necessary?

- **21 C.F.R. § 314.107(c)(3) ("If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval.")**

THANK YOU!!
FDA Law Blog
(www.FDAlawblog.net)