

FDA Works to Increase Competition Under Commissioner's Drug Competition Action Plan

Agency works to speed approvals and improve access to generic prescription drugs.

In recent weeks, the US Food and Drug Administration (FDA or the Agency) has taken a series of steps — under FDA Commissioner Scott Gottlieb's Drug Competition Action Plan — to encourage the development of generic prescription drug products with the goal of lowering prescription drug prices. For example, on June 27, 2017, the FDA issued a news release announcing the publication of a list of off-patent, off-exclusivity drugs without approved generics.¹ In the same news release, FDA announced an internal policy revision governing prioritization of Agency review of original abbreviated new drug applications (ANDAs), amendments, and supplements to expedite review of generic drug applications when competition is limited.² According to FDA Commissioner Gottlieb, these actions “are the first of a series of steps the [FDA] intends to take to help” patients afford the cost of prescription drugs.³

These statements closely follow the FDA's June 22, 2017 announcement of a planned public meeting, “The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access.”⁴ The meeting — scheduled for July 18, 2017— will provide an opportunity for the public to submit comments concerning the administration of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). The stated purpose is “to help ensure the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained.”⁵

FDA's recent regulatory actions are consistent with the Trump Administration's recent focus on the pharmaceutical industry. Indeed, media reports indicate that President Trump is currently considering a draft executive order, “Reducing the Cost of Medical Products and Enhancing Biomedical Innovation,” which targets the pharmaceutical industry and the high cost of prescription drugs.⁶ Thus, additional changes — aimed at speeding access to generic drug products and decreasing prices — are likely forthcoming.

New FDA Leadership Demonstrates Commitment to Addressing Prescription Drug Pricing

Although the FDA has historically been reluctant to address prescription drug product pricing, new FDA Commissioner Gottlieb's actions suggest that the Agency has recently adopted a new approach. As discussed above, FDA's July 27, 2017 press release outlines two FDA actions designed to speed access to generic drugs:

- (i) Publishing a list of off-patent, off-exclusivity drugs without approved generics

- (ii) Issuing a revised internal policy governing the prioritization of FDA review of original ANDAs, amendments, and supplements

A discrete change to an FAQ section on the FDA website further demonstrates changing Agency priorities. The Center for Drug Evaluation and Research (CDER) FAQ page previously stated that, “FDA has no legal authority to investigate or control the prices charged for marketed drugs” and “factors beyond its purview” determine drug pricing.⁷ However, FDA recently updated the CDER FAQ page, explaining, “the agency is committed to facilitating increased competition in the market for prescription drugs through the approval of lower-cost generic medicines.”⁸ Together, these actions suggest that the FDA has embraced a new approach to addressing prescription drug prices.

FDA Publishes List of Off-Patent, Off-Exclusivity Drugs Without Approved Generics

When FDA published its list of more than 250 off-patent, off-exclusivity drugs without approved generics, the Agency explained that the list was issued “[t]o improve transparency and encourage the development of abbreviated new drug applications (“ANDAs”) in markets with no competition.”⁹ In the list methodology description, FDA states that a given ingredient (or combination of ingredients) is included on the list if:

- (a) At least one active and approved NDA for the ingredient is present
- (b) There are no approved ANDAs for the ingredient
- (c) No patents or exclusivities are listed for the NDAs¹⁰

The FDA then places each ingredient and corresponding NDA numbers in either Part I or Part II of the list.¹¹ Part I of the list “identifies those drug products for which FDA could immediately accept an ANDA without prior discussion.”¹² Part II “identifies drug products involving potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to submission of an ANDA.”¹³ The FDA clarifies in its explanation of the list methodology, that the list considers products by their Orange Book-listed active ingredient, and does not differentiate between different strengths or dosage forms of products with the same listed active ingredient (although the FDA identified corresponding NDA numbers for these products to assist applicants in identifying the correct reference listed drug (RLD)).¹⁴ Further, as it is too soon to gauge ANDA submission, the list excludes any NDA drug products approved within the past year. Interested stakeholders should continually monitor this list as the FDA plans to update it every six months.¹⁵

FDA Issues New Priority Review Policy for Review of Generic Drugs

FDA’s June 27, 2017 press release also announced a change to the FDA’s policy governing how the Agency — specifically, CDER’s Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ) — prioritizes review of generic drug applications.¹⁶ Before issuing the revised Manual of Policies and Procedures (MAPP), the FDA prioritized only the first generic product for which there were no blocking patents or exclusivities on the reference listed drug (RLD).¹⁷ By contrast, updated MAPP 5240.3 Rev. 3, “Prioritization of the Review of Original ANDAs, Amendments, and Supplements” explains that going forward the Agency “will expedite the review of generic drug applications until there are three approved generics for a given drug product.”¹⁸ FDA made this revision “based on data indicating that consumers see significant price reductions when there are multiple FDA-approved generics available.”¹⁹ As such, the revised MAPP 5240.3 greatly expands the ability of generic drug manufacturers to obtain priority review of new generic drug products.

FDA Plans Public Meeting Focused on Innovation Versus Access

On June 22, 2017, the FDA published a Federal Register notice (the Notice) announcing that the Agency planned to hold a meeting on July 18, 2017, “The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access.”²⁰ In the Notice, the FDA explained that “[o]ver the past several years, the Agency has undertaken major initiatives to expand access to quality, affordable generic medicines.”²¹ FDA states that under the proposed Generic Drug User Fee Amendments II Commitment Letter, “FDA would further enhance the ANDA review program by clarifying regulatory expectations early in product development, helping applicants develop more complete submissions, and giving applicants more opportunities to address deficiencies within a review cycle, all with the goal of reducing the number of review cycles necessary to obtain ANDA approval.”²²

However, the FDA also observes in the Notice that “the legal framework surrounding these exclusivities may have been applied to delay generic competition to an extent that may not have been intended by the Hatch-Waxman Amendments, and in ways that may not serve the public health.”²³ To illustrate, FDA identifies the practice of innovators who “have made late changes in patent use codes that create new obstacles to previously acceptable labelling carveouts.”²⁴ Similarly, in a June 21, 2017 FDA Voice blog post accompanying the Notice, FDA Commissioner Gottlieb identified several ways that pharmaceutical companies have “gamed” the Agency’s regulatory rules.²⁵ For example, Commissioner Gottlieb called out branded companies that use regulatory strategies or commercial techniques to deliberately attempt to block a generic company from accessing testing samples (e.g., use of restrictions in commercial contracts or agreements with distributors to make it harder for intermediaries in the drug supply chain to sell the drugs to generic drug developers). Also, the FDA Voice blog post noted that the Agency has observed that generic drug manufacturers have experienced difficulty accessing testing samples when branded products are subject to limited distribution, regardless of whether the company has voluntarily adopted limitations on distribution, or the limitations have been imposed as part of a Risk Evaluation and Mitigation Strategy (REMS).²⁶

In view of these concerns, the Notice indicates that the FDA is soliciting input from the public concerning how to preserve the balance struck by Congress between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs. Among other topics and questions, the FDA requests stakeholder input on the following:

- How have exclusivity periods, patents (including patent listing procedures), innovator drug product labeling, post-approval changes to innovator products (e.g., reformulations), and other regulatory processes (e.g., the citizen petition process) impacted the balance of innovation and access set forth in the Hatch-Waxman Amendments?
- Given that more than half of all FDA-approved ANDAs are never marketed, marketed only after a substantial delay after approval, or marketed only intermittently, what marketplace dynamics disincentivize the marketing of approved drug products? What should FDA do, within its statutory authority, to help more approved generics reach consumers?
- Why is it the case that for approximately 10% of all innovator drugs, patent and exclusivity protections have expired, but FDA has not received an ANDA? Are the incentives provided by the Hatch-Waxman Amendments insufficient to support ANDA development in certain market niches? What should FDA do, consistent with its legal authority, to encourage submissions in any such market?

- How should FDA apply its statutory authority to waive the requirement that Risk Evaluation and Mitigation Strategies (REMSs) that include elements to assure safe use (ETASU) be implemented through a “single shared system,” or develop other administrative tools, to avoid these delays?
- What additional actions should FDA take, within its legal authority, to promote access to innovator drug products for generic companies seeking to conduct studies required to support ANDA submissions?
- What other elements of drug product development, regulation, and marketing have the potential to disrupt the Hatch-Waxman Amendments’ balance between innovation and generic availability, and how should the Agency and other stakeholders address them?

The Notice indicates that the deadline for members of the public to submit comments regarding this meeting is September 8, 2017. It further notes that requests for oral presentations must be made to the FDA contact person by July 3, 2017.

Administration Circulates Draft Executive Order Focused on Reducing Cost of Medical Products and Enhancing Biomedical Innovation

As referenced above, a draft executive order, “Reducing the Cost of Medical Products and Enhancing American Biomedical Innovation” has recently been circulating in the media and trade press.²⁷ The draft executive order directs FDA to “take steps to advance innovation and encourage lower-cost alternatives in order to enhance access to safe and effective medical product options for patients.”²⁸ These actions are designed to, among other things, “increase drug competition,” “enable generic entry for complex drugs,” and “address unintended consequences of existing rules that may reduce competition.”²⁹ Notably, the executive order also states that it will be Executive Branch policy to “[f]acilitate, where appropriate, the ability of Federal health programs to enter into reimbursement arrangements for medical products that are based on the value of such products to patients rather than the volume of such products purchased.”³⁰ This is significant because the idea of value-based pricing (*i.e.*, paying drug companies for the value a drug delivers to patients) has been embraced by industry and policy analysts alike. Although the executive order is still in draft form and remains subject to change, it nevertheless provides insight into the Trump Administration’s current thinking regarding steps to address exorbitant prescription drug costs.

New FDA Leadership Committed to Fostering Competition and Reducing Prescription Drug Prices

In sum, FDA’s new leadership is dedicated to speeding approvals for, and increasing access to, generic prescription drug products. The Agency’s recent regulatory activities, FDA Commissioner Gottlieb’s stated commitment to pursuing additional actions to address the high cost of prescription drugs, and the draft executive order addressing efforts to reduce the cost of medical products all demonstrate FDA’s renewed focus on these issues. This provides industry an opportunity to engage with the Agency and actively shape the leadership’s regulatory vision. Regulated industry should consult with counsel to determine the best way to engage with the FDA regarding this new area of focus.

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Endnotes

¹ FDA News Release: FDA Tackles Drug Competition to Improve Patient Access (June 27, 2017), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm564725.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery (last visited June 29, 2017).

² *Id.*

³ *Id.*

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- 11 *Id.*
- 12 *Id.*
- 13 *Id.*
- 14 *Id.*
- 15 *Id.*
- 16 FDA News Release: FDA Tackles Drug Competition to Improve Patient Access (June 27, 2017), *supra* note 1; *See also* FDA, CDER, Manual of Policies and Procedures (“MAPP”) 5240.3 Rev. 3 – Prioritization of the Review of Original ANDAs, Amendments, and Supplements (effective June 27, 2017), available at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf> (last visited June 29, 2017).
- 17 *Compare Id.*; FDA, CDER, Manual of Policies and Procedures (“MAPP”) 5240.3 Rev. 2 – Prioritization of the Review of Original ANDAs, Amendments, and Supplements (effective Mar. 11, 2016), available at <https://web.archive.org/web/20170405202640/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf> (last visited June 29, 2017).
- 18 FDA, CDER, Manual of Policies and Procedures (“MAPP”) 5240.3 Rev. 3 – Prioritization of the Review of Original ANDAs, Amendments, and Supplements (effective June 27, 2017), available at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf> (last visited June 29, 2017).
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- 21 *Id.* at 28494.
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- 24 *Id.*
- 25 Scott Gottlieb, M.D., FDA Voice: FDA Working to Lift Barriers to Generic Drug Competition (June 21, 2017), available at <https://blogs.fda.gov/fdavoices/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/> (last visited June 29, 2017).
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