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Client Alert Commentary

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Food and Drug Omnibus Reform Act Introduces Key Changes to FDA's Authorities

The legislation contains several reforms to FDA's statutory authority and the regulatory framework that it administers.

Key Points:

- Omnibus legislation appropriates new funds to FDA and reauthorizes certain FDA programs.
- Legislation also amends FDA's statutory authorities to reform aspects of the FDA regulatory framework.

On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (the Act), which contains the Food and Drug Omnibus Reform Act (FDORA).[1] The Act passed in the Senate by a vote of 68-29 and in the House of Representatives by a vote of 225-201.[2] The Act provides approximately $6.56 billion in total funding for the US Food and Drug Administration (FDA) for fiscal year (FY) 2023, of which approximately $3.53 billion is congressionally-appropriated funding.[3] The other $3.03 billion will come from revenue collected from FDA's user fee programs.[4]

FDORA follows the September 30, 2022 enactment of the Continuing Appropriations Act, 2022 (Continuing Appropriations Act), which reauthorized FDA's prescription drug, generic drug, biosimilar biological product, and medical device user fee programs through FY 2027 without material reforms to the FDA regulatory framework. Historically, the reauthorization of these user fee programs has been a catalyst for negotiation regarding material amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) and Public Health Services Act (PHSA) and an opportunity to reform the FDA regulatory framework. However, Congress did not reach an agreement on such reforms ahead of enactment of the Continuing Appropriations Act. The Continuing Appropriations Act also provided for approximately 10 weeks of appropriations for most government agencies. FDORA contains several changes to the FDA regulatory framework that were originally proposed in connection with the user fee reauthorization negotiations and continued to be negotiated during the short-term funding period provided in the Continuing Appropriations Act.[5]

Appropriations and Creating/Reauthorizing FDA Programs

The Act provides for $6.56 billion in total FDA funding, of which approximately $3.53 billion is appropriated funding, a roughly 6.5% increase in appropriated funding over fiscal year 2022.[6] An additional $3.03 billion of FDA's budget will come from the agency's authorized user fee programs.[7]

Specifically, the Act provides for $1.31 billion in funding from prescription drug and biological product user fees, $324.78 million from medical device user fees, $582.5 million from generic drug user fees, $41.6 million in biosimilar biological product user fees, $32.14 million in new animal drug user fees, $29.3 million in generic animal drug user fees, and $712 million in tobacco product user fees.[8]

The Act reauthorizes several existing FDA programs and authorities through October 2027. Specifically, FDORA reauthorizes:

- the critical path public-private partnership, a program under which FDA may enter into collaborative agreements with eligible entities to foster medical product innovation; accelerate medical product development, manufacturing, and translational therapeutics; and enhance medical product safety;[9]
- the best pharmaceuticals for children program, which is designed to incentivize certain pediatric clinical studies;[10]
- the humanitarian device exemption incentive, which exempts the manufacturers of certain qualifying devices marketed pursuant to humanitarian device exemptions from the general prohibition on selling such devices for amounts that exceed the costs of research and development, fabrication, and distribution of such devices;[11]
- the pediatric device consortia program, a grant or contract program for nonprofit consortia to conduct demonstration projects to promote pediatric device development;[12]
- a provision of Section 505 of the FDCA concerning certain drugs containing a single enantiomer;[13]
- accredited persons inspection program, under which manufacturers of certain devices may voluntarily request inspection by an accredited third party;[14]
- the orphan products grants program, through which FDA awards grants to certain clinical investigators to support the development of safe and effective medical products for patients with rare diseases;[15]
- reporting requirements related to pending generic drug applications and priority review applications;[16] and
- the 510(k) third-party review program, through which FDA-recognized third parties may review premarket notifications for certain devices and recommend initial classifications of such devices.[17]

FDORA also creates new programs, including an emerging technology program that is intended to support the adoption of innovative approaches to drug design and manufacturing.[18] Additionally, FDORA establishes an unannounced foreign facility inspection pilot program under which the agency will increase unannounced surveillance inspections of foreign human drug establishments.[19]

Changes to FDA's Authorities and Its Regulatory Framework

In addition to appropriating funds to FDA and reauthorizing agency programs, FDORA amends the FDCA and PHSA to effect other reforms, which may significantly impact FDA-regulated industries and other stakeholders. For example, one of FDORA's key reforms involves changing the accelerated approval framework, including authorizing FDA to require a post-approval study or studies be underway prior to, or

within a specific timeframe of, accelerated approval.[20] The statute also clarifies the circumstances in which two interchangeable biosimilar biological products may share first interchangeable exclusivity.[21]

Notably, FDORA also contains key legislative changes expanding FDA's regulatory authorities over cosmetic products. In particular, FDORA amends the FDCA to require registration with FDA of cosmetic manufacturing or processing facilities and listing of cosmetic products associated with such facilities.[22] Cosmetic product manufacturers will also be subject to certain adverse event reporting and record retention requirements, as well as safety substantiation requirements.[23] The law further requires FDA to promulgate regulations establishing current good manufacturing practice requirements for cosmetics manufacturing.[24] Finally, FDORA provides FDA with new authorities to enforce these provisions, including mandatory recall authority over cosmetic products.[25]

FDORA further amends the FDCA to provide changes to the circumstances under which FDA will assign therapeutic equivalence ratings for certain prescription drugs approved via the Section 505(b)(2) New Drug Application (NDA) pathway[26] and to amend the definition of a qualified infectious disease product to include certain products authorized via the Biologics License Application (BLA) pathway.[27] FDORA also requires FDA to establish an advanced manufacturing technologies designation program and to expedite the development and review of NDAs and BLAs, including NDA and BLA supplements, for products manufactured using a designated advanced manufacturing technology.[28]

Takeaways

In addition to providing FDA with FY 2023 funding, the Act amends the FDCA and PHSA in ways that could have important implications for industry and other stakeholders. Several of these reforms may require FDA to take additional action, such as through notice and comment rulemaking or through the publication of guidance documents, providing additional opportunities for direct stakeholder engagement.

While the Act contains several key reforms, other proposed changes to the FDA regulatory framework were ultimately not included in the Act, including proposals regarding dietary supplements and the regulation of certain in vitro diagnostic tests. Industry and other stakeholders should continue to closely monitor both FDA action in exercising these new authorities and implementing new or reauthorized programs, as well as congressional action with respect to other proposed legislative changes to FDA's authorities and the regulatory programs it administers.

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Endnotes

[1] *See* Bill Signed: H.R. 2617, https://www.whitehouse.gov/briefing-room/legislation/2022/12/16/press-release-bill-signed-h-r-1437/ (December 29, 2022).

[2] *See* H.R. 2617, 117th Cong. (2022). Rep. Rashida Tlaib (D-MI) voted present.

[3] *See* Division A, Title VI.

[4] *See id*.

[5] The appropriations provided by the Continuing Appropriations Act lapsed after December 16, 2022. On December 16, 2022, President Biden signed the Further Continuing Appropriations Act, 2023, which extended appropriations through December 23, 2022, during which period Congress continued to negotiate the Act. *See* Bill Signed: H.R. 1437, https://www.whitehouse.gov/briefing-room/legislation/2022/12/16/press-release-bill-signed-h-r-1437/ (Dec. 16, 2022). On December 23, 2022, President Biden signed the Further Additional Continuing Appropriations and Extensions Act, 2023, a further extension to appropriations through December 30, 2022. *See* Bill Signed: H.R. 4373, https://www.whitehouse.gov/briefing-room/legislation/2022/12/23/press-release-bill-signed-h-r-4373/ (Dec. 16, 2022).

[6] *See* Division A, Title VI.

[7] *See id*.

[8] *See id*.

[9] *See* Division FF, Title III, Subtitle A, Section 3101.

[10] *See* Division FF, Title III, Subtitle A, Section 3102.

[11] *See* Division FF, Title III, Subtitle A, Section 3103.

[12] *See* Division FF, Title III, Subtitle A, Section 3104

[13] *See* Division FF, Title III, Subtitle A, Section 3105.

[14] *See* Division FF, Title III, Subtitle A, Section 3106.

[15] *See* Division FF, Title III, Subtitle A, Section 3107.

[16] *See* Division FF, Title III, Subtitle A, Section 3108.

[17] *See* Division FF, Title III, Subtitle A, Section 3109.

[18] *See* Division FF, Title III, Subtitle B, Chapter 1, Section 3203.

[19] *See* Division FF, Title III, Subtitle F, Chapter 2, Section 3615.

[20] *See* Division FF, Title III, Subtitle B, Chapter 1, Section 3210.

[21] *See* Division FF, Title III, Subtitle B, Chapter 1, Section 3206.

[22] *See* Division FF, Title III, Subtitle E, Section 3502.

[23] *See id*.

[24] *See id*.

[25] *See id*.

[26] *See* Division FF, Title III, Subtitle B, Chapter 2, Section 3222.

[27] *See* Division FF, Title III, Subtitle B, Chapter 1, Section 3212.

[28] *See* Division FF, Title III, Subtitle B, Chapter 1, Section 3213.