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Client Alert Commentary

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FDA Omnibus Reform Act: Examining the Policy Changes

The Act introduces key reforms to the FDA regulatory framework relating to drugs, biological products, and cosmetics, among others.

On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (the Act),[1] which passed in the House of Representatives by a vote of 225-201 and in the Senate by a vote of 68-29.[2] While central provisions of the Act concern federal appropriations, including appropriations to the Food and Drug Administration (FDA), the Act also contains the Food and Drug Omnibus Reform Act of 2022 (FDORA), which contains material amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) and Public Health Service Act (PHSA). FDORA thus reforms the FDA regulatory framework relating to drugs, biological products, medical devices, and cosmetics, among others.

FDORA represents the culmination of years of negotiation among FDA, industry, consumer groups, and other stakeholders. Notably, FDORA omits certain proposed changes found in FDA user fee reauthorization bills or other legislation introduced but not enacted in 2022, such as the Verifying Accurate Leading-edge IVCT Development Act (VALID Act),[3] which would have created a new FDA-regulatory product category of in vitro diagnostic tests, subject to a new premarket review framework; proposed changes to the scope of orphan drug exclusivity; and proposed changes to the dietary supplement regulatory framework.[4]

This Client Alert examines certain key provisions of FDORA.

Drugs and Biologics Development and Approval Reforms

Therapeutic Equivalence Evaluations

Section 3222 of the Act amends Section 505(j)(7)(A) of the FDCA[5] to require FDA to reach a therapeutic equivalence rating determination for prescription drugs approved via the 505(b)(2) New Drug Application (NDA) pathway "for which the sole difference from a listed drug relied upon in the application is a difference in inactive ingredients" which render the product ineligible for approval via an abbreviated new drug application (ANDA).[6] FDA will now reach a therapeutic equivalence determination for such products "at the time of approval of such application or not later than 180 days after the date of such approval."[7] Previously, 505(b)(2) NDA holders could request a therapeutic equivalence determination through the citizen petition process. For qualifying 505(b)(2) NDAs *submitted prior to the date of enactment but not yet approved*, the evaluation "shall be made not later than 180 days after the date of approval of such application if an evaluation request is submitted as an amendment to" the NDA.[8] For qualifying 505(b)(2)

NDAs *approved prior to the date of enactment*, Section 3222 provides that the therapeutic equivalence "evaluation shall be made not later than 180 days after receipt of a request for a therapeutic equivalence evaluation submitted as part of a supplement to" the already-approved NDA.[9]

Modernizing Accelerated Approval

Section 3210 of the Act amends the accelerated approval framework at Section 506(c) of the FDCA.[10] Specifically, the Act (1) requires FDA to publish a rationale on its website any time the Agency does not require a post-approval study for a product approved under accelerated approval; (2) requires FDA to specify the conditions for a post-approval study or studies no later than the date of product approval; (3) allows FDA to require post-approval studies to be underway prior to approval or within a specified time period after the date of approval; and (4) codifies the expedited procedures FDA may use in withdrawing approval of an accelerated approval product.[11]

The Act amends Section 506B(a) of the FDCA[12] to require sponsors of drugs approved under the accelerated approval framework to submit a report detailing progress on any required post-approval studies no later than 180 days after approval, and every 180 days thereafter until the studies are completed or terminated.[13] The Act also requires FDA to post information about the progress of these studies on FDA's website. The Act provides FDA with enforcement authority for a sponsor's failure to conduct post-approval studies of accelerated approval products with due diligence, or to submit timely reports with respect to such products in accordance with the aforementioned requirement.[14]

Additionally, the Act directs FDA to issue draft guidance within 18 months after enactment of the Act on topics related to accelerated approval and the development of products for accelerated approval, including identification of novel surrogate or intermediate clinical endpoints, use of surrogate or intermediate clinical endpoints, use of novel clinical trial designs for post-approval studies, and expedited procedures that FDA may use to withdraw approval of an accelerated approval product.[15] Further, the Act requires FDA to establish an Accelerated Approval Council no later than one year after enactment of the Act. The council will be responsible for engaging with product review teams to support consistent and appropriate use of accelerated approval across FDA.[16]

Advancing Qualified Infectious Disease Product Innovation

Section 3212 of the Act amends Section 505E of the FDCA[17] to make qualified infectious disease products (QIDPs) authorized via the PHSA Section 351(a) Biologics License Application (BLA) pathway eligible for the five-year extension of any existing exclusivity provided by the Generating Antibiotic Incentives Now (GAIN) Act.[18] Previously, only products approved via the NDA pathway were eligible for GAIN Act exclusivity. The Act also amends FDCA Section 524A(a)[19] to expand eligibility for QIDP priority review to include biological products seeking approval via a Section 351(a) BLA,[20] but also amends Section 524A(a) to limit priority review to the first application (either NDA or BLA) submitted for approval for a specific QIDP that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness.[21]

Clarifications to Exclusivity Provisions for First Interchangeable Biosimilar Biologics

Section 3206 of the Act amends Section 351(k)(6) of the PHSA[22] to address non-patent exclusivity for interchangeable biosimilar biological products.[23] Specifically, the Act amends the PHSA to clarify that multiple interchangeable biosimilar biological products may share first interchangeable exclusivity if licensed on the same day.[24] This framework aligns with FDA's approach with respect to small-molecule drug 180-day exclusivity.

Encouraging Development of Advanced Manufacturing Technologies

Advanced Manufacturing Technologies Designation Program

Section 3213 of the Act creates a new FDCA Section 506L, which directs FDA to initiate an Advanced Manufacturing Technologies Designation Program no later than one year from the date of enactment. The program establishes a process for designation of methods of manufacturing drugs (including biological products) and active pharmaceutical ingredients of such drugs as "advanced manufacturing technologies."[25] A manufacturing method (or combination of methods) is eligible for designation as an advanced manufacturing technology if it "incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug while maintaining equivalent, or providing superior, drug quality" (e.g., by reducing drug development time or increasing/maintaining supply of certain drugs).[26]

To obtain such a designation, the requestor must submit data or information demonstrating that the method of manufacturing meets the above criteria.[27] FDA will then respond to the request no later than 180 calendar days after the receipt.[28] NDAs, BLAs, and NDA and BLA supplements using the designated technology are eligible for expedited development and review.[29] The holder of an advanced manufacturing technology designation is also allowed to reference or rely on data and information about the designated technology for use in manufacturing drugs in the same context of use for which the designation was granted in future applications.[30]

The Act requires FDA to hold a public meeting to obtain input from stakeholders within 180 days of enactment regarding the goals, scope, framework, procedures, and requirements of the Advanced Manufacturing Technologies Designation Program and the ways in which FDA will support the use of advanced manufacturing innovations.[31] FDA must issue draft guidance regarding the goals and implementation of the program no later than 180 days after the public meeting, and must issue final guidance no later than two years after enactment.[32] The Act also directs FDA to publish a report on its website containing a description and evaluation of the program, including the types of innovative manufacturing approaches supported under the program, no later than three years after enactment of the Act and annually thereafter.[33] Lastly, the Act contains a sunset provision preventing FDA from considering any requests for designation submitted after October 1, 2032. However, FDA will be allowed to continue activities under the program for technologies designated prior to such date if FDA "determines such activities are in the interest of the public health."[34]

Cosmetic Product Regulatory Reform

FDORA contains the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which significantly expands FDA's authority over the manufacture and marketing of cosmetic products.[35] MoCRA identifies certain compliance deadlines and also directs FDA to publish notices of proposed and final rulemaking to implement certain of these requirements.

Expansion of Cosmetic Requirements

Section 3502 of the Act creates new legal requirements applicable to cosmetic products by adding Sections 604-614 to Chapter VI of the FDCA,[36] including the following:

- **Adverse event reporting and recordkeeping:** Section 605 requires, among other things, that responsible persons (i.e., manufacturers, packers, or distributors whose name appears on the label of the product) submit to FDA any report of a serious adverse event (SAE) associated with the use of a

cosmetic product in the US that was "manufactured, packed, or distributed by such person" within 15 business days after receipt of such report.[37] The Act requires the responsible person to maintain records of all adverse events reports for six years or, if the responsible person meets the definition of "small business" as set forth in Section 612, three years. The responsible person must permit FDA access to such records upon request during an inspection.[38]

- **Good manufacturing practice:** Section 606 requires FDA to promulgate regulations that establish good manufacturing practices (GMPs) for facilities engaged in the manufacturing or processing of cosmetic products distributed in the US. FDA must publish a notice of proposed rulemaking within two years of the date of enactment and a final rule no later than three years after the date of enactment.[39]

- **Facility registration and product listing:** Section 607 establishes new facility registration and product listing requirements. Under the Act, every person who owns or operates a facility engaged in the manufacturing or processing of a cosmetic product for distribution in the US[40] must register such facility with FDA.

  Facilities already engaging in the manufacturing or processing of a cosmetic product for distribution in the US as of the date of enactment must register within one year of the date of enactment of MoCRA.[41] New facilities that begin engaging in the manufacturing or processing of a cosmetic product for distribution in the US[42] after the date of enactment must register within 60 days of first engaging in such activities or 60 days after the deadline for registering existing facilities (whichever is later).[43]

  The responsible person must submit to FDA a cosmetic product listing that includes facility registration number(s), contact information of the responsible person, the name of the cosmetic product(s), the applicable cosmetic category or categories, a list of ingredients in the cosmetic product (including fragrances, flavors, or colors), and the product listing number (if any) assigned by FDA.[44] Cosmetic product listings must be submitted to FDA within one year for products that were already being marketed on the date of enactment of MoCRA.[45] For cosmetic products first marketed after the date of enactment, a responsible person must submit a cosmetic product listing to FDA within 120 days of marketing such product in the US. Updates to cosmetic product listings must be submitted annually.[46]

  FDA is authorized to suspend a facility registration upon a reasonable belief that cosmetic products manufactured or processed by a registered facility and distributed in the US have a reasonable probability of causing serious adverse health consequences or death to humans and that other products manufactured or processed by the facility may be similarly affected.[47] If a facility's registration is suspended, the facility may not introduce or deliver for introduction into US commerce any cosmetic product until the suspension is vacated and the facility registration is reinstated.[48]

- **Safety substantiation:** Section 608 requires that a responsible person ensure and maintain records supporting adequate substantiation of a cosmetic product's safety. Adequate substantiation of safety is defined as "tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe."[49] However, the Act clarifies that a cosmetic will not be deemed unsafe "solely because it can cause minor and transient reactions or minor and transient skin irritations in some users."[50]

- **Labeling:** Section 609 sets forth new labeling requirements, including contact information of the responsible person to enable receipt of adverse event reports and identification of any fragrance

allergens. MoCRA provides FDA with authority to determine, by regulation, which substances are considered fragrance allergens.[51] This section also sets forth specific labeling requirements for cosmetic products intended for professional use, including that the labels bear a "clear and prominent statement that the product shall be administered or used only by licensed professionals."[52]

- **Records:** Section 610 permits FDA to request from each responsible person and facility access to and copies of all records relating to certain cosmetic products reasonably believed to be adulterated "such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans."[53] FDA is also authorized to request records for "any other cosmetic product that [FDA] reasonably believes is likely to be affected in a similar manner."[54] Under this section, only records that are "needed to assist [FDA] in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans" may be requested.[55]

- **Mandatory recall authority:** Section 611 provides FDA with mandatory recall authority over certain cosmetic products determined with reasonable probability to be "adulterated under section 601 or misbranded under 602 and the use of or exposure to such cosmetic product will cause serious adverse health consequences or death."[56] FDA must first provide the responsible person with the opportunity to voluntarily cease distribution and recall the affected cosmetic products within the time and manner prescribed by FDA prior to ordering the immediate cessation of distribution of such cosmetic products.[57]

For a product meeting the definition of both a drug and a cosmetic under the FDCA, MoCRA provides that the FDCA's drug requirements will generally supersede the cosmetic requirements.[58] However, a product regulated as both a drug and a cosmetic must comply with the new fragrance allergen and professional-use labeling requirements. [59]

Enforcement and Conforming Amendments

Section 3503 of the Act amends Section 301 of the FDCA[60] to provide FDA with enforcement authority for failure to register or submit listing information or to abide by a mandatory recall order.[61] It also makes conforming amendments to several sections of the FDCA related to cosmetic product adulteration, misbranding, and adverse event reporting.[62]

Records Inspection

Section 3504 of the Act amends Section 704(a)(1) of the FDCA[63] by clarifying that when inspecting a facility that manufactures or processes cosmetic products, FDA is authorized to inspect records and other information described in Sections 605 (adverse events), 606 (good manufacturing practice), and 610 (records) if the relevant standard for records inspection under such section is met.[64]

Unannounced Foreign Facility Inspections Pilot Program

Section 3615 directs FDA to initiate a pilot program that "increases the conduct of unannounced surveillance inspections of foreign human drug establishments."[65] As part of the pilot program, FDA must evaluate certain differences between inspections of foreign and domestic human drug establishments and assess the effect of providing advance notice of inspections to persons who own/operate foreign human drug establishments. The scope of this pilot program is limited to routine surveillance inspections and therefore excludes inspections conducted as part of a human drug marketing approval request. FDA must initiate this pilot program within 180 days after the enactment of the Act.[66]

Conclusion

FDORA contains substantive provisions that could have a widespread and significant impact on the pharmaceutical, biotechnology, and cosmetics industries, such as expediting the development and approval of certain drug products and mandating cosmetic product serious adverse event reporting. Stakeholders should continue to monitor how FDA's new regulatory authorities will be implemented. FDA's efforts to promulgate regulations and develop guidance documents implementing these new authorities present stakeholders opportunities for meaningful engagement to shape the future of these regulatory programs.

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Endnotes

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

[2] H.R. 2617, 117th Cong. (2022); *Biden Signs $1.7 Trillion Bill Funding Government Operations*, PBS (Dec. 30, 2022, 2:27 PM), https://www.pbs.org/newshour/politics/biden-signs-1-7-trillion-bill-funding-government-operations.

[3] *See* S. 4348, 117th Cong. (2022).

[4] On June 8, 2022, by a 392-28 vote, the House of Representatives passed H.R. 7667, the Food and Drug Amendments of 2022, which, if enacted, would have revised and extended FDA's user fee programs. The bill proposed changes to the legal standards of the FDCA concerning FDA's accelerated approval pathway and the scope of orphan drug exclusivity, but did not include other changes, such as the VALID Act or any changes to the dietary supplement regulatory framework. On May 26, 2022, members of the Senate Committee on Health, Education, Labor, and Pensions (HELP), Committee Chair Patty Murray, and ranking member Richard Burr introduced H.R. 7667's corresponding Senate bill, S.4348 (the Food and Drug Administration Safety and Landmark Advancements Act of 2022 (FDASLA)), in order to revise and extend FDA's user fee programs. FDASLA proposed the same changes to the legal standards of the FDCA as H.R. 7667, but also included other changes, such as changes to the dietary supplement regulatory framework and the VALID Act. However, FDASLA did not pass in the Senate.

[5] 21 U.S.C. § 355(j)(7)(A).

[6] *See* H.R. 2617-1371, Division FF, Title III, Subtitle B, Section 3222.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] 21 U.S.C. § 356(c).

[11] *See* Division FF, Title III, Subtitle B, Section 3210.

[12] 21 U.S.C. § 356b(a).

[13] *See id.*

[14] *See id.*

[15] *Id.*

[16] *Id.*

[17] 21 U.S.C. § 355f.

[18] *See* 21 U.S.C. § 355f(a).

[19] 21 U.S.C. § 360n-1(a).

[20] *See* Division FF, Title III, Subtitle B, Section 3212.

[21] *See id.*

[22] 42 U.S.C. § 262(k)(6).

[23] *See* Division FF, Title III, Subtitle B, Section 3206.

[24] *See id.*

[25] *See* Division FF, Title III, Subtitle B, Section 3213 (adding Section 506L to Chapter V of the FDCA (21 U.S.C. § 351 et seq.)).

[26] *Id.*

[27] *See id.*

[28] *See id.*

[29] *See id.*

[30] *See id.*

[31] *See id.*

[32] *See id.*

[33] *See id.*

[34] *Id.*

[35] *See* Division FF, Title III, Subtitle E, Section 3501.

[36] 21 U.S.C. § 361 et seq.

[37] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 605 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)).

[38] *Id.*

[39] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 606 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)). Establishments that qualify as small businesses under the Act will be exempt from such GMP requirements. *See id*.

[40] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 607 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)). However, the Act omits from the definition of "facility" certain establishments that engage in the manufacturing or processing of cosmetic products, such as certain beauty shops and salons, that meet the specified criteria.

[41] *Id*.

[42] *See id.* Establishments that qualify as small businesses under the Act are exempt from the Section 607 registration and product listing requirements. *See id*.

[43] *See id*.

[44] *See id*.

[45] *See id.*

[46] *See id*.

[47] *See id*.

[48] *See id*.

[49] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 608 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)); *see also* Division FF, Title III, Subtitle E, Section 3503(a)(2).

[50] *Id*.

[51] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 609 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)).

[52] *Id*.

[53] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 610 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)).

[54] *Id*.

[55] *Id*.

[56] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 611 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.)).

[57] *See id*.

[58] *See* Division FF, Title III, Subtitle E, Section 3502 (adding Section 613 to Chapter VI of the FDCA (21 U.S.C. § 361 et seq.))

[59] *See id*.

[60] 21 U.S.C. § 331.

[61] *See* Division FF, Title III, Subtitle E, Section 3503.

[62] *See id*.

[63] 21 U.S.C. § 374(a)(1).

[64] *See* Division FF, Title III, Subtitle E, Section 3504

[65] *See* Division FF, Title III, Subtitle F, Section 3615.

[66] *See id*.