



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0198]

#### Mark Moffett; Conviction Reversal; Final Order Withdrawing Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), withdrawing its January 25, 2023, order debarring Mark Moffett from providing services in any capacity to a person with an approved or pending drug product application. FDA is issuing this order because the U.S. Court of Appeals for the First Circuit vacated Mr. Moffett's convictions and sentence.

**DATES:** The order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In a document published in the *Federal Register* on January 25, 2023 (88 FR 4826), Mark Moffett was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262). The debarment was based on FDA's finding, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), that Mr. Moffett had been convicted of a felony under Federal law for conduct relating to the regulation of any drug product.

Mr. Moffett appealed the judgment of the District Court, and on November 18, 2022, the U.S. Court of Appeals for the First Circuit issued a judgment vacating Mr. Moffett's convictions as to all counts. On January 26, 2023, Mr. Moffett petitioned FDA for withdrawal of his debarment, citing section 306(d)(3)(B)(i) of the FD&C Act. Pursuant to section 306(d)(3)(B)(i) of the FD&C Act, "If the conviction which served as the basis for the debarment of an individual under subsection (a)(2)...is reversed, the Secretary shall withdraw the order of debarment."

FDA has concluded that because the U.S. Court of Appeals for the First Circuit vacated Mr. Moffett's convictions, the order of debarment must be withdrawn. Accordingly, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(d)(3)(B)(i) of the FD&C Act, under authority delegated to the Assistant Commissioner, is issuing this order withdrawing the order that permanently debarred Mark Moffett from providing services in any capacity to a person with an approved or pending drug product application.

Dated: July 10, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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