



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1992-N-0199]

David J. Brancato: Grant of Special Termination; Final Order Terminating Debarment

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 (the FD&C Act) granting special termination of the debarment of David J. Brancato. FDA bases this order on a finding that Dr. Brancato provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Dr. Brancato's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments should reference Docket No. FDA-1992-N-0199 and be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM-4144), Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION: In a Federal Register notice dated January 6, 1994 (59 FR 00751), David J. Brancato, a former review chemist with FDA's Division of Generic Drugs was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)). The debarment was based on FDA's finding that Dr. Brancato was convicted of a felony under Federal law for conduct relating to the development, or approval of any drug product, or otherwise relating to the regulation of a drug product. On May 26, 1998, Dr. Brancato applied for special termination of debarment, under section 306(d)(4) of the FD&C Act, as amended by the Generic Drug Enforcement Act. On April 15, 2015, the Agency requested additional information. On April 20, 2015, Dr. Brancato provided the requested information.

Under section 306(d)(4)(C) and (d)(4)(D) of the FD&C Act, FDA may limit the period of debarment of a permanently debarred individual if the Agency finds that: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in section 306(a) or (b) of the FD&C Act or relating to a matter under FDA's jurisdiction; (2) termination of the debarment serves the interest of justice; and (3) termination of the debarment does not threaten the integrity of the drug approval process.

Special termination of debarment is discretionary with FDA. FDA generally considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases. Dr. Brancato cooperated with the United States Attorney's Office in the investigation of several individuals, as substantiated by letters submitted to the Agency by Thomas Holland, a Special Agent in the Office of the Inspector General, U.S. Department of Health and Human Services, and the U.S. Attorney's Office for the District of Columbia. His cooperation contributed to the successful prosecution of these individuals, and in

one instance continued over a period of 7 years. Accordingly, FDA finds that Dr. Brancato provided substantial assistance as required by section 306(d)(4)(C) of the FD&C Act.

The additional requisite showings, i.e., that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process, are difficult standards to satisfy. In determining whether these have been met, the Agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that Dr. Brancato was convicted for a first offense; that he has no prior or subsequent convictions for conduct described under the FD&C Act and has committed no other wrongful acts affecting the drug approval process; and that his character and scientific accomplishments are highly regarded by his professional peers. The evidence presented supports the conclusion that the conduct upon which Dr. Brancato's debarment was based is unlikely to recur. For these reasons, the Agency finds that termination of Dr. Brancato's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the FD&C Act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Brancato's period of debarment, which commenced on January 6, 1994, has lasted more than 1 year. Accordingly, the Director of the Office of Enforcement and Import Operations, under section 306(d)(4) of the FD&C Act and under authority delegated to the

Director (Staff Manual Guide 1410.35), finds that David J. Brancato's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Director of Enforcement and Import Operations further finds that because the Agency is granting Dr. Brancato's application, an informal hearing under section 306(d)(4)(C) of the FD&C Act is unnecessary.

As a result of the foregoing findings, Dr. David J. Brancato's debarment is terminated effective (see DATES) (21 U.S.C. 335a(d)(4)(C) and (d)(4)(D)).

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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