present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in September or October 2015.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, health care professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on PDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all stakeholder consultation discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly stakeholder consultation meetings after notifying FDA of this intention (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 736B(d)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding PDUFA reauthorization, please provide notification by email to *PDUFAReauthorization@fda.hhs.gov* by August 28, 2015. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: July 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17684 Filed 7–17–15; 8:45 am]

BILLING CODE 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 July 20, 2015.

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.

[FR Doc. 2015–17712 Filed 7–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Extension of Nomination Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of nomination period.

SUMMARY: The Food and Drug Administration (FDA) is extending the nomination period for the notice that appeared in the **Federal Register** of May 19, 2015. In the notice, FDA requested nominations for a list of bulk drug substances that may be used by facilities registered as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs from bulk substances, in accordance with FDA's draft guidance for industry (GIF) #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' The FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit nominations.

DATES: Submit either electronic or written nominations for the bulk drug substances list by November 16, 2015.

ADDRESSES: You may submit nominations by any of the following methods:

Electronic Submissions

Submit electronic nominations in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written nominations in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2015–N–1196. All nominations received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or nominations received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration (HFV–210), 7519 Standish Pl., Rockville, MD 20855, 240–402–5745, *neal.bataller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 2015 (80 FR 28622), FDA published a notice with a 90-day nomination period for the list of bulk drug substances that may be used by a facility registered as an outsourcing facility under section 503B of the FD&C Act (21 U.S.C. 353B) to compound drugs for use in animals in accordance with FDA's draft GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' That notice describes the information that should be provided to the FDA in support of each nomination.

FDA has received a request for a 90-day extension of the nomination period as the requestor wanted more time to nominate drugs to the list and to provide supporting data. FDA has considered the request and is extending the nomination period for 90 days, until November 16, 2015. The FDA believes that a 90-day extension allows adequate time for interested persons to submit nominations without significantly delaying consideration of these nominations.

II. Nomination Process

The process for nominations for bulk drug substances that may be used by facilities registered as outsourcing facilities under section 503B of the FD&C Act to compound animal drugs from bulk drug substances is described in the previous notice published May 19, 2015. FDA cannot guarantee that all drugs nominated during the nomination period will be considered for initial inclusion in Appendix A at the time of its initial publication. Nominations submitted during the nomination period (ending on November 16, 2015) that are not evaluated and included in Appendix A at the time of its initial publication will receive consideration for later addition to Appendix A. In addition, individuals and organizations may petition FDA, in accordance with 21 CFR 10.30, to make additional amendments to Appendix A after the nomination period.

III. Request for Nominations

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in brackets in the heading of this document. Received nominations may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*