

TABLE 2—ESTIMATED BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Sample outgo (pretests and main survey) .....	16,384	.....	.....	.....	.....
Screener completes .....	1,638	1	1,638	.03 (2 minutes)	49
Eligible .....	1,556	.....	.....	.....	.....
Completes, Pretest 1 .....	252	1	252	.5 (30 minutes)	126
Completes, Pretest 2 .....	252	1	252	.5 (30 minutes)	126
Completes, Main Study .....	495	1	495	.5 (30 minutes)	248
Completes, Pretest 3 .....	108	1	108	.25 (15 minutes)	27
Completes, Followup Study .....	216	1	216	.25 (15 minutes)	54
Total .....	.....	.....	.....	.....	630

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

## References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Lee, M. and Y.C. Lou, "Consumer Reliance on Intrinsic and Extrinsic Cues in Product Evaluations: A Conjoint Approach," *Journal of Applied Business Research*, 12(1), pp. 21–29 (2011).
2. Teas, R.K. and S. Agarwal, "The Effects of Extrinsic Product Cues on Consumers' Perceptions of Quality, Sacrifice, and Value," *Journal of the Academy of Marketing Science*, 28(2), pp. 278–290 (2000).
3. Rao, A.R. and K.B. Monroe, "The Effect of Price, Brand Name, and Store Name on Buyers' Perceptions of Product Quality: An Integrative Review," *Journal of Marketing Research*, pp. 351–357 (1989).
4. Mitra, A., J.L. Swasy, and K.J. Aikin, "How Do Consumers Interpret Market Leadership Claims in Direct-to-Consumer Advertising of Prescription Drugs?" *Advances in Consumer Research*, 33, pp. 381–387 (2006).
5. O'Donoghue, A., H.K. Sullivan, D. Aikin, R. Chowdhury, et al., "Presenting Efficacy Information in Direct to Consumer Prescription Drug Advertisements," *Patient Education Counsel*, 95(2), pp. 271–80 (2014).
6. Schwartz, L.M., S. Woloshin, and H.G. Welch, "Using a Drug Facts Box to Communicate Drug Benefits and Harmstwo Randomized Trials," *Annals of Internal Medicine*, 150(8), pp. 516–527 (2009).
7. Sullivan, H.W., A. C. O'Donoghue, and K.J. Aikin, "Presenting Quantitative Information About Placebo Rates to Patients," *JAMA Internal Medicine*, doi: 10.1001/jamainternmed.2013.10399 (2013).

Dated: July 15, 2015.

**Leslie Kux,**

Associate Commissioner for Policy.

[FR Doc. 2015–17725 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–2010–N–0128]

#### Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

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

**ACTION:** Notice; request for notification of participation.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

**DATES:** Submit notification of intention to participate in these series of meetings by August 28, 2015. Stakeholder

meetings will be held monthly. It is anticipated that they will commence in September or October 2015.

**ADDRESSES:** Submit notification of intention to participate in monthly stakeholder meetings by email to [PDUFAReauthorization@fda.hhs.gov](mailto:PDUFAReauthorization@fda.hhs.gov). The meetings will be held at the FDA campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

**FOR FURTHER INFORMATION CONTACT:** Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA V) expires in September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(d) of the FD&C Act (21 U.S.C. 379h–2(d)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 15, 2015, where stakeholders and other members of the public will be given an opportunity to

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](mailto: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]

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## 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