

Section 306(d)(4)(C) of the FD&C Act does not define “substantial assistance.” When FDA has granted requests for special termination of debarment, however, it has stated that the Agency “considers a determination by the [United States] Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases” (see, e.g., 68 FR 58352 (October 9, 2003)). The U.S. Department of Justice typically determines whether an individual has provided substantial assistance in accordance with section 5K1.1 of the U.S. Sentencing Guidelines (USSG) during the sentencing phase of a Federal criminal trial. Section 5K1.1 states, “Upon motion of the government stating that the defendant has provided substantial assistance in the investigation or prosecution of another person who has committed an offense, the court may depart from the [sentencing] guidelines.” Rule 35(b) of the Federal Rules of Criminal Procedure and 18 U.S.C. 3553(e) also permit a court to depart from the guideline range or a statutory minimum sentence upon motion by the government if the defendant “provided substantial assistance in investigating or prosecuting another person.” The Generic Drug Enforcement Act (GDEA) amended the FD&C Act to provide FDA with debarment authority. The language in section 306(d)(4)(C) of the FD&C Act, which was included in the GDEA in response to a request from the U.S. Department of Justice (see 138 Cong. Rec. S5614 (April 10, 1992) (statement of Sen. Kennedy)), clearly mirrors the forgoing language applicable to Federal criminal defendants.

Much of the conduct to which Mr. Bhutani points as the basis for claiming that he has provided “substantial assistance in investigations or prosecutions” of offenses within the jurisdiction of FDA occurred before his sentencing in 2000. Mr. Bhutani, however, does not provide any evidence that the U.S. Department of Justice moved for a downward departure on the basis of a substantial assistance determination under USSG section 5K1.1 when he was sentenced for the convictions that triggered his permanent debarment. Furthermore, even assuming that FDA could grant special termination of an individual’s debarment under section 306(d)(4)(C) of the FD&C Act if the government has never moved a court for downward departure on the basis of substantial assistance, the conduct described by Mr. Bhutani does not suffice to show substantial assistance in the sense contemplated by that statutory

provision. Mr. Bhutani merely claims that he voluntarily provided some information about the offenses he and his own company, Alra, committed and that he cooperated with FDA in resolving outstanding civil matters involving Alra and him on two separate occasions.

Although section 306(d)(4)(C) of the FD&C Act does not explicitly specify that the substantial assistance must be for the investigation or prosecution of another person’s offenses, the appropriate statutory interpretation should be consistent with “substantial assistance” when used as a “term of art”¹ in the context of criminal proceedings. (See *Sullivan v. Stroop*, 496 U.S. 478, 483 (1990) (holding that, “where a phrase in a statute appears to have become a term of art, * * * any attempt to break down the term into its constituent words is not apt to illuminate its meaning”). As noted above, USSG section 5K1.1, Rule 35(b) of the Federal Rules of Criminal Procedure and 18 U.S.C. 3553(e) permit a court to depart from the guideline range or a statutory minimum sentence upon motion by the government if the defendant “provided substantial assistance in investigating or prosecuting another person.” FDA therefore construes “substantial assistance in the investigations or prosecutions of offenses” to require that the assistance be provided with respect to another person’s offenses.

As a result, under section 306(d)(4)(C) of the FD&C Act, the information provided by Mr. Bhutani about his own offenses, and those of his own company, very early in a criminal investigation does not qualify as substantial assistance. Likewise, Mr. Bhutani’s assertions that he decided to resolve pending regulatory issues with FDA by entering into consent agreements that required him and his company to comply with the law do not show that he provided substantial assistance in the investigation or prosecution of offenses of another person. In fact, all Mr. Bhutani claims to have done was decide to take steps to comply with the law after he had violated it. Such steps clearly do not constitute substantial assistance in the investigation or prosecution of offenses.

III. Conclusion

Therefore, the Chief Scientist, under authority delegated to him, denies Mr. Bhutani’s application for special

termination of debarment under section 306(d)(4)(C) of the FD&C Act. A hearing on this request is not necessary because there are no genuine and substantial issues of fact (see 21 CFR 16.26(a)).

Any person with an approved or pending drug product application who knowingly uses the services of Mr. Bhutani, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Bhutani provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Bhutani during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))).

Dated: December 10, 2012.

Jesse L. Goodman,
Chief Scientist.

[FR Doc. 2012–30709 Filed 12–20–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel: Stress, Pain and the Biologic Response to Surgery.

Date: January 17–18, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20814.

Contact Person: John Firrell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301–435–2598, firrellj@csr.nih.gov.

¹ See *United States v. Ellis*, 527 F.3d. 203, 206 (1st Cir. 2008) (holding that “substantial assistance,” in the context of original sentencing, is a term of art and that the meaning of the term in USSG section 5K1.1 and Rule 35(b) is the same).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 14, 2012.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–30716 Filed 12–20–12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the NCI-Frederick Advisory Committee.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. The premature disclosure of information to be discussed during the meeting would significantly frustrate implementation of a proposed agency action.

Name of Committee: NCI-Frederick Advisory Committee.

Date: February 4, 2013.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: Discussion of Proposed Frederick National Laboratory for Cancer Research Strategic Plan.

Place: The Lawrence Berkeley National Laboratory—Department of Energy, Perseverance Hall, Building 54, Room 130A, 1 Cyclotron Road, Berkeley, CA 94720.

Contact Person: Thomas M. Vollberg, Sr., Ph.D., Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 7th Floor, Room 7142, Bethesda, MD 20892–8327, (301) 694–9582.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 14, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–30715 Filed 12–20–12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Brain Trauma.

Date: January 4, 2013.

Time: 11:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Samuel C Edwards, Ph.D., I RG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, edwards@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 17, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–30718 Filed 12–20–12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: NHLBI Systems Biology.

Date: January 17–18, 2013.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, zouai@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Vector and Eukaryotic Pathogens.

Date: January 22–23, 2013.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20892, (301) 435–1149, elzaataf@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Integrative, Functional, and Cognitive Neuroscience: Member Conflicts: Cocaine, Alcohol and Reward.

Date: January 23–24, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892, 301–435–1119, mselectmanoff@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group Biochemistry and Biophysics of Membranes Study Section.

Date: January 23, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.