including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medicated Feed Mill Licensing Application—21 CFR Part 515 (OMB Control Number 0910–0337)—Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at 21 CFR part 515.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated Feed Mill License Application Using Form FDA 3448 (§ 515.10(b))	20	1	20	.25	5
Supplemental Feed Mill License Application Using Form FDA 3448 (§ 515.11(b))	40	1	40	.25	10
Voluntary Revocation of Medicated Feed Mill License (§ 515.23)	40	1	40	.25	10
Filing a Request for a Hearing on Medicated Feed Mill License (§ 515.30(c))	1	1	1	4	4
Total					29

[1] There are no capital costs or maintenance costs associated with this information collection.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of responses per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Labeling (§ 510.305)	950	1	950	0.03	28.5

[1] There are no capital costs or maintenance costs associated with this information collection.

Estimated annual reporting burden on industry is 29 hours as shown in table 1. Industry estimates it takes about 15 minutes (.25) to submit the application. We estimate 100 original and supplemental applications, and voluntary revocations for a total of 25 hours (100 submissions × .25 (15 minutes)). An additional 4 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 28.5 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated .03 hours for each of approximately 950 licensees. Total burden for reporting and recordkeeping would be 57.5 hours.

Dated: December 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30738 Filed 12–20–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2002–N–0106 (formerly 2002N–0291)]

Baldev Raj Bhutani; Denial of Hearing on Application for Special Termination of Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Baldev Raj Bhutani's application for special termination of debarment under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Mr. Bhutani has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective December 21, 2012.

ADDRESSES: Comments should reference Docket No. FDA–2002–N–0106 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: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire

Ave., Silver Spring, MD 20993, 301–796–4613.

SUPPLEMENTARY INFORMATION:

I. Background

Mr. Bhutani is the former President and Treasurer of Alra Laboratories, Inc. (Alra), a drug company. On February 12, 1996, in the U.S. District Court for the Northern District of Illinois-Eastern Division, Mr. Bhutani was found guilty of one count of conspiracy, a Federal felony offense under 18 U.S.C. 371, and six other Federal felonies related to violations under sections 301(a), (e), and (k) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a), (e), and (k) and 333(a)(2)). The basis for these convictions was Mr. Bhutani's conduct surrounding his company's manufacture and distribution of the drug products LACTULOSE Syrup and K + 10. According to the records of Mr. Bhutani's criminal proceedings, he and Alra violated the FD&C Act by, inter alia, including decomposed raw material in finished drug products and deviating from approved manufacturing procedures by adding an undocumented substance, sodium hydroxide, to drug products in an unapproved manner. On October 12, 1999, Mr. Bhutani also pled guilty to one count of wire fraud, a Federal felony under 18 U.S.C. 1343. On February 15, 2000, the district court sentenced Mr. Bhutani for his felony convictions. On December 2, 2004, pursuant to section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), FDA permanently debarred Mr. Bhutani based on the foregoing Federal felony convictions (see 69 FR 70148 (Dec. 2, 2004)). As a result of his debarment, Mr. Bhutani may not provide services in any capacity to a person with an approved or pending drug product application under section 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).

On August 18, 2010, Mr. Bhutani applied for special termination of debarment under section 306(d)(4) of the FD&C Act. Under sections 306(d)(4)(C) and (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.

By a letter dated March 2, 2011, the Director of the Office of Enforcement, Office of Regulatory Affairs (the Director) offered Mr. Bhutani an opportunity for a regulatory hearing under 21 CFR part 16 on a proposal to deny his application for special termination of debarment. In the letter, the Director set forth his determination that Mr. Bhutani's application did not demonstrate that he provided substantial assistance in investigations or prosecutions of any offenses related to any matter within the jurisdiction of FDA in accordance with section 306(d)(4)(C) of the FD&C Act. In a submission received April 7, 2011, Mr. Bhutani requested a hearing on the Director's proposed denial of his application.

Under § 16.26(a), FDA may deny a request for a hearing upon a determination that ''no genuine and substantial issue of fact has been raised by the material submitted.'' The Chief Scientist has reviewed Mr. Bhutani's request for a hearing, as well as the materials submitted in support of that request, and concludes that Mr. Bhutani's request for a hearing fails to raise any genuine and substantial issues of fact requiring a hearing and that his application for termination of debarment does not satisfy any of the statutory grounds for termination.

II. Arguments

In his application for termination of debarment, Mr. Bhutani argues that FDA should terminate his debarment under section 306(d)(4) of the FD&C Act for a number of reasons, including many focusing on the fairness of the criminal convictions underlying his permanent debarment under section 306(a)(2). Section 306(d) of the FD&C Act describes the circumstances under which FDA may terminate an individual's debarment. Under section 306(d)(3)(B)(i) of the FD&C Act, FDA must withdraw an order debarring an individual upon reversal of the criminal conviction or convictions forming the basis for his or her debarment. Section 306(d)(3)(B)(ii) of the FD&C Act provides that FDA must grant an application for termination of debarment submitted by an individual under 306(d)(1) ''if such termination serves the interests of justice and adequately protects the integrity of the drug approval process,'' but only if the individual was subjected to permissive debarment under section 306(b)(2)(B) or (b)(3). In fact, section 306(d)(1) of the FD&C Act specifies that an individual permanently debarred may not submit such an application. Finally, under section 306(d)(4) of the FD&C Act, FDA may grant an individual's application for special termination of debarment upon a finding that he or she ''has provided substantial assistance in the investigations or prosecutions of offenses which are described in [section 306(a) or (b)] or which relate to any matter under the jurisdiction of [FDA]'' (see section 306(d)(4)(C)).

Inasmuch as FDA permanently debarred Mr. Bhutani under section 306(a)(2) of the FD&C Act, based on his Federal felony convictions for conduct related to drug products, he is only eligible for termination of debarment if: (1) The convictions underlying his debarment were overturned (see section 306(d)(3)(B)(i)) or (2) he has provided substantial assistance in the investigations or prosecutions of offenses which are described in section 306(a) or (b) or which relate to a matter within FDA's jurisdiction (see section 306(d)(4)(C)). Mr. Bhutani has presented no reason to believe that a court has overturned the felony convictions on which his permanent debarment was based. If a court were to overturn his convictions based on the arguments Mr. Bhutani now makes with respect to the fairness and validity of those convictions, however, FDA would withdraw the order debarring him. The sole remaining issue is whether Mr. Bhutani is eligible for special termination of debarment under section 306(d)(4)(C) of the FD&C Act, and to be so eligible he must have provided substantial assistance in the sense contemplated by that provision.

In his application for termination of debarment and request for a hearing, Mr. Bhutani argues that his debarment should be terminated on the grounds that he provided substantial assistance and cooperated with FDA in related investigations regarding Alra's compliance with FDA's current good manufacturing practices (cGMP) regulations and offered his full support to bring his own company, Alra, into cGMP compliance. Mr. Bhutani asserts that he and Alra twice entered consent decrees with FDA, both in 1991 and 1999, that required the correction of many of the violations of the FD&C Act underlying his felony convictions. Mr. Bhutani contends that, in accordance with those consent decrees, he worked cooperatively with FDA to ensure that Alra was manufacturing and distributing drugs in compliance with the FD&C Act. He also claims that, in 1991, he provided some of the information to investigators that led to his own criminal convictions and the criminal investigation and prosecution of Alra and him.

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

[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).

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.*