DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PROCEEDING ON THE PROPOSAL TO DENY

THE PETITION OF SANYASI RAJU KALIDINDI

FOR SPECIAL TERMINATION OF DEBARMENT

In this proceeding under 21 CFR part 16, the Food and Drug Administration's (FDA's or the Agency's) Office of Regulatory Affairs (ORA), pursuant to section 306(d) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 335a(d)), proposes to deny Sanyasi Raju Kalidindi's (the petitioner's) application for special termination of debarment (current petition) and provides notice to Dr. Kalidindi of the opportunity to request a hearing on the proposal.

As FDA's Chief Scientist, I have the delegated authority to issue a decision in this matter. *See* Staff Manual Guide 1410.21. Based on my review of the administrative record, I find that there is no genuine and substantial issue of fact with respect to whether the petitioner provided "substantial assistance" or whether termination of his debarment here would "best serve[] the interest of justice and protect[] the integrity of the drug approval process," as contemplated by section 306(d)(4) of the FD&C Act. As this decision further explains below, because there exists no genuine and substantial issue of fact to resolve at a hearing, I also deny Dr. Kalidindi's request for a hearing as unnecessary. 21 CFR 16.26(a).

After a consideration of all the undisputed material facts in the administrative record, pursuant to section 306(d) of the FD&C Act, I conclude that granting Dr. Kalidindi's current petition best serves the interest of justice and protects the integrity of the drug approval process. Accordingly, I grant the current petition for special termination of debarment.

I. Background

On April 21, 1993, FDA permanently debarred the petitioner from providing services in any capacity to a person with an approved or pending drug product application under sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act. FDA based the debarment on its finding under section 306(a)(2) of the FD&C Act that the petitioner had been 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 27, 1998, FDA denied Dr. Kalidindi's previous petition for special termination of debarment and maintained debarment at the statutory maximum for permanent debarment.

On January 13, 2020, Dr. Kalidindi submitted the current petition under section 306(d)(4) of the FD&C Act. The petition states that the petitioner provided substantial assistance to the government in several ways, thus satisfying section 306(d)(4)(C) of the FD&C

Act, which provides that debarred individuals may have their debarment terminated upon petition if the petition shows that they "provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) or which relate to any matter under the jurisdiction of [FDA]." The petition asserts that terminating his debarment serves the interest of justice and would pose no threat to the integrity of the drug approval process. The petitioner states that he has had no convictions for FDA-related matters since his debarment and that terminating his debarment would allow him to contribute to the integrity of the drug approval process by assisting the drug industry with its quality control efforts by using his patents and expertise.

On April 10, 2020, FDA's Office of Regulatory Affairs (ORA) proposed denying the current petition and offered the petitioner an opportunity to request a hearing on the proposal to deny. ORA notes in its proposal that, in its summary denial of Dr. Kalidindi's previous petition for special termination of debarment, FDA found that the petitioner provided "substantial assistance" in the investigations or prosecutions of offenses described in section 306(a) or 306(b) of the FD&C Act or which relate to any matter under the jurisdiction of FDA, as required by section 306(d)(4)(C). ORA does not revisit that prior Agency finding and states that the only question for FDA is to determine whether special termination of the petitioner's debarment would best serve the interest of justice and would not threaten the integrity of the drug approval process.

In its April 10, 2020, proposal to deny the current petition, ORA further finds that a consideration of all available favorable and unfavorable information in light of the remedial public health purposes underlying the debarment statute should result in a denial of the current petition. ORA gives great weight to the nature and seriousness of the offense involved as well as the petitioner's culpability for the conduct underlying his conviction. While acknowledging that ORA has no information that the petitioner engaged in criminal activity since his conviction, ORA emphasizes the gravity of the criminal conduct that led to the debarment. ORA determines that the seriousness of this offense does not support a conclusion that the petitioner does not pose a threat to the integrity of the drug approval process. ORA also emphasizes that the petitioner's original conviction involved the use of his supervisory position and his use of extensive scientific training to violate the law.

On May 9, 2020, the petitioner requested a hearing, and on June 8, 2020, he submitted supplemental materials to the hearing request, consisting of letters of reference from employees and information on company standard operating procedures, patents, and clinical study information.

II. Analysis

A. Request for a hearing

FDA may deny a request for a hearing, in whole or in part, under 21 CFR 16.26(a), upon a finding that the information or arguments submitted do not raise a genuine and substantial issue of fact. The standard for denying a hearing in 21 CFR 16.26(a) aligns with the standard in federal court for summary judgment. *See Hess* & *Clark, Div. of Rhodia, Inc. v. Food* & *Drug Admin.,* 495 F.2d 975, 983 (1974) (While discussing an FDA order withdrawing approval of a new animal drug application, the court stated, "When the FDA issues a Notice of Opportunity for Hearing, its summary judgment procedures are available if the requesting party fails to raise material issues of fact."). A material factual dispute is one that would affect the outcome of the proceeding.

The primary purpose of a regulatory hearing under Part 16 is to resolve factual questions and obtain additional information before the Commissioner makes a decision or takes an action. 21 CFR 16.1. As stated in the preamble of the final rule,"[i]f a genuine and substantial issue of fact has not been shown to exist, any remaining issues of law and policy surrounding an agency action or proposed action are not matters to be resolved in a fact-finding hearing. . . . Under such circumstances a hearing would not serve any useful purpose: the issues of law and policy will be resolved by the decisionmaker on the basis of applicable statutory provisions, regulations and policies." 53 Fed. Reg. 4614, Feb. 17, 1988. When the petitioner fails to raise any substantial issues of fact in a request for a hearing under Part 16, FDA has the authority under 21 CFR 16.26(a) to deny the request for a hearing. When there are no material factual disputes and an informal hearing is not therefore justified, Part 16 does not contemplate that a hearing will be granted when not warranted.

After an evaluation of the administrative record, including both ORA's and the petitioner's submissions, I conclude that there exists no material factual dispute that would warrant a hearing under Part 16 to resolve. Based on reasoning set forth below, I find that there is no genuine and substantial issue of fact with respect to whether the petitioner provided "substantial assistance" or whether terminating his debarment here would "best serve[] the interest of justice and protect[] the integrity of the drug approval process," as contemplated by section 306(d)(4) of the FD&C Act. Inasmuch as I am granting the relief requested by the petitioner based on the undisputed record before me, a hearing is unnecessary, and I am thus denying the petitioner's hearing request.

B. Special Termination of Debarment

Section 306(d)(4) of the FD&C Act provides that any individual debarred under section 306(a)(2) may apply to FDA for special termination of debarment. Pursuant to section 306(d)(4)(C)-(D), FDA may grant a request for special termination and limit the period of debarment to less than permanent but no less than one year if the Agency finds: (1) that the individual has provided substantial assistance in the investigations or prosecutions of offenses described in section 306(a) or (b) , or relating to any matter under the jurisdiction of FDA and (2) that doing so best serves the interest of justice and protects the integrity of the drug approval process. Consistent with section 306(d)(4), FDA has significant discretion to grant a request for special termination of debarment when the individual provided a qualifying form of substantial assistance.

In the instant matter, it is undisputed that the petitioner provided substantial assistance in the investigations or prosecutions of others for offenses described in section 306(a) or (b) of the FD&C Act, as contemplated by section 306(d)(4)(C) or otherwise relating to FDA's jurisdiction. As conceded by ORA in its proposal to deny the current petition, the Agency previously found that the petitioner provided such substantial assistance in a decision dated May 27, 1998, with respect to a previous petition filed by Dr. Kalidindi. In that previous decision, FDA noted that the United States Department of Justice (DOJ) had determined that the petitioner provided substantial assistance and that FDA considers a determination by DOJ to be conclusive in most cases. Before denying the previous petition on other grounds, the Agency determined that the petitioner's "cooperation was substantial and satisfies the test of section 306(d)(4)(C) of the [FD&C] Act." In proposing to deny the current petition, ORA explicitly indicates that it does not wish to revisit the Agency's previous finding that the petitioner provided a qualifying form of substantial assistance under section 306(d)(4)(C).

Consistent with the Agency's rationale for denying Dr. Kalidindi's previous petition, ORA nonetheless concludes that the Agency should deny the current petition on the ground that granting it would not best serve the interest of justice and protect the integrity of the drug approval process, as required under section 306(d)(4)(D) of the FD&C Act. Likewise following the rationale provided by FDA in denying Dr. Kalidindi's previous petition, ORA's analysis hinges on "whether special termination of [the petitioner's] debarment would best serve the interest of justice and *would not threaten* the integrity of the drug approval process" (emphasis added). In determining that the petitioner has not met that standard, ORA relies extensively on the Agency's previous summary of the surrounding conduct leading to Dr. Kalidindi's 1993 conviction for one count of aiding and abetting the making of a false statement in a matter within the jurisdiction of a Federal agency in violation of 18 U.S.C. 1001 and 2. In short, ORA states that the petitioner falsified records related to drug manufacturing with the intention of concealing information from FDA and used his position of authority as a supervisor to direct others to falsify records in a similar manner. In addition, ORA notes that the Assistant U.S. Attorney stated that the petitioner submitted false information to FDA on other occasions. The

petitioner does not dispute any of those proposed findings based on the facts established at his criminal proceeding, as recited by FDA in the decision from 1998.

ORA is clearly correct that section 306(d)(4) of the FD&C Act requires the Agency to go past a finding that a debaree provided a qualifying form of substantial assistance in evaluating a request for special termination. But in applying the statutory language in section 306(d)(4)—which hinges on whether terminating debarment would "protect[] the integrity of the drug approval process"—ORA focuses on finding that terminating a *specific individual's* debarment would not "threaten" the integrity of the drug approval process, consistent with the Agency's long-standing approach to this issue. Although this interpretation of section 306(d)(4) is reasonable and consistent with precedent, my own view is that adopting a more expansive interpretation of that provision—particularly with respect to whether granting special termination would "protect[] the integrity of the drug approval process" by limiting the period of debarment—should take into account both the nature of the substantial assistance provided and the overall effect on the drug approval process that terminating debarment under such circumstances would have. Given the high level of substantial assistance provided by the petitioner and the broader protection of the drug approval process afforded by limiting individuals' periods of debarment as a general matter when they have provided meaningfully significant substantial assistance, I conclude that exercising that broader standard of discretion under section 306(d)(4) to grant the current petition is appropriate in this case.

A fundamental canon of statutory construction requires that a statute be read as a harmonious whole, with its various provisions interpreted within their broader statutory context in a manner that furthers statutory purposes. "The plainness or ambiguity of statutory language is determined by reference to language itself, the specific context in which the language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997). Nonetheless, a "proper construction frequently requires consideration of [a statute's] wording against the background of its legislative history and in the light of the general objectives Congress sought to achieve." *Wirtz v. Bottle Blowers Ass'n*, 389 U.S. 463, 468 (1968).

With respect to the plain language of the statute, the wording of section 306(d)(4) itself evinces a congressional intent to provide FDA broad discretion both to grant and deny requests for special termination. Both "best serves the interest of justice" and "protects the integrity of drug approval process" are expansive standards that would appear to confer on the Agency the authority to account for a wide range of considerations. Indeed, as the Supreme Court has repeatedly held, the language in the FD&C Act should be construed in a manner that is consistent with its overall public health purpose. "[W]hen we are dealing with the public health, the language of the [FD&C Act] should not be read too restrictively, but rather as consistent with the Act's overriding purpose to protect the public health." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Expanding the considerations here to include more than whether a specific individual poses some threat to the drug approval process and to

permit a broader focus on the impact on the drug approval process in general is consistent with that objective.

When viewed in the context of the legislative history of the Generic Drug Enforcement Act, which provided FDA with the debarment authority at stake here, the broader contours of section 306(d)(4)(D) of the FD&C Act become even clearer. The legislative history supports a reading that the "substantial assistance" provision in section 306(d)(4)(C) of the FD&C Act was intended to provide a means of protecting the overall integrity of the drug approval process. According to the legislative history, the overall objective behind section 306(d)(4) was to permit DOJ and FDA to obtain cooperation from any individuals who might have violated laws related to the regulation of drugs. In a statement submitted to the congressional record, Senator Edward M. Kennedy noted the following:

> The bill contains a provision allowing for possible early termination of debarment for individuals who provided substantial assistance in investigations or prosecutions of offenses of the [FD&C Act]. This modification of the House passed bill was done in response to a request from the Department of Justice and provides the FDA and Federal prosecutors with more flexibility to obtain cooperation in investigations and prosecutions than would otherwise be available." 138 Cong. Rec. S5614, April 10, 1992.

In other words, individuals might be unwilling to provide substantial assistance in connection with a felony guilty plea to secure a lighter sentence if the conviction would compel permanent exclusion from the drug industry. Congress appears to have recognized in the debarment context that obtaining information about criminal acts related to the regulation of drugs was vital to protecting the integrity of the drug approval process. Indeed, the inclusion of the provision in the law allowing for the possibility of early termination of debarment for persons who provided substantial assistance in investigations or prosecutions of violations of the FD&C Act appears to reflect Congress's view that incentivizing substantial assistance helps protect the integrity of the drug approval process.

Such an objective becomes even more pronounced when the provided substantial assistance was significant, as is the case here. In the present case, not only did the petitioner provide substantial assistance, but by all accounts, he provided a high level of substantial assistance. Even in denying Dr. Kalidindi's previous petition for special termination, FDA highlighted statements in the record of the petitioner's criminal proceedings in the United States District Court for the District of Maryland establishing that the petitioner's cooperation exceeded the typical efforts by a criminal defendant when the government argues for a lesser sentence based on a finding of substantial assistance. In conveying DOJ's finding that the petitioner provided substantial assistance, the Assistant U.S. Attorney stated:

> The point I really wanted to make about Mr. Kalidindi . . . is that on every occasion where we asked Mr. Kalidindi to come down to talk to us, our time was

> his time. He fully availed himself to our needs, spent many days being debriefed, gave us many good leads. We had a lot of effective investigative and prosecutorial steps taken because of his cooperation. He worked undercover on the Botzolakis case and performed masterfully. I just want the Court to understand that from our perspective this man has done as much as the government ever expects of a cooperator and I hope that the Court will reward him accordingly.

Before sentencing the petitioner to three years of probation and five hundred hours of community service, the court also praised the level of the petitioner's cooperation:

> I think the government has recognized your tremendous help to them and certainly you should be rewarded for it. I think in the investigation there have only been a handful of people who have really gone all out to help the government . . . A lot of them attempted to cover up or, when they came forward, they came forward only when someone else had come forward and given their names and just had nothing to get. But in your case they say you even went undercover for Mr. Botzolakis, so I think that's in addition to what most of them have done.

In evaluating the current petition, considering the petitioner's high level of substantial assistance would not only serve the interest of justice under section 306(d)(4)(D) but also "protect[] the integrity of the drug approval process." Granting special termination to the petitioner—and other similarly situated debarees—based partly on the level and scope of substantial assistance—would incentivize others implicated in investigations related to the drug approval process to provide substantial assistance to DOJ and FDA in both investigating and prosecuting violations of the FD&C Act. It is no doubt important to examine the threat of a specific individual to the drug approval process based on the egregiousness of the conduct surrounding his criminal conviction. But to focus almost exclusively on such a threat —i.e., without weighing that conduct against the level and scope of a petitioner's substantial assistance—would hinder DOJ and FDA's ability to secure such cooperation in the future and thus undermine the protection of the drug approval process as a general matter. We would diminish the willingness of potential criminal defendants—including those who have committed serious offenses—to provide substantial assistance in furtherance of the investigation or prosecution of offenses related to the drug approval process or the regulation of drugs as a whole. Those individuals implicated in criminal offenses would risk mandatory and permanent exclusion from the drug industry with no assurance that their cooperation would receive due consideration by FDA in evaluating a request for special termination. By failing to weigh the nature and scope of substantial assistance against the nature and scope of the conduct underlying the criminal offense in evaluating such a request, we would thus undermine protection of the drug approval process and the regulation of drugs in general by limiting the government's effectiveness in investigating and prosecuting criminal offenses related to those

areas of concern. In fact, without those cooperating witnesses, FDA's ability to mitigate the effects of such criminal offenses would be limited because the Agency might have less information about the specifics of those offenses.

In evaluating the petitioner's request for special termination, ORA's proposal to deny special termination does not examine the scope and level of the substantial assistance provided. Instead, it declines to address the petitioner's substantial assistance other than to concede that the Agency has previously determined that the petitioner provided a qualifying form of substantial assistance under section 306(d)(4)(C) of the FD&C Act. As noted above, ORA's proposal then focuses on the nature and scope of the conduct underlying the original conviction and emphasizes the serious nature of that conduct. To a limited extent, the proposal to deny the current petition weighs that criminal conduct against the information and arguments submitted by the petitioner with respect to his conduct since FDA debarred him in 1993. However, ORA appears to treat only the fact that there is no reason to believe that the petitioner has committed criminal offenses in that time as a favorable factor and explicitly qualifies its consideration of that factor by pointing to the petitioner's exclusion from the drug industry during the same period. ORA then emphasizes, "The mere passage of time does not diminish the impact and seriousness of your conduct."

As a preliminary matter, I note that the "mere passage of time" is arguably a material consideration here because the inquiry under section 306(d)(4) of the FD&C Act is not simply on whether FDA should terminate the petitioner's debarment but on whether it should limit his debarment period. Given that the petitioner has already been debarred for more than twenty-eight years, the question becomes whether his debarment should be limited to that period based on the considerations described above—i.e. whether granting his request for special termination of debarment best serves the interest of justice and protects the integrity of the drug approval process in a general sense—not whether he should have served a lesser period of time closer to the one year mandated by section 306(d)(4)(D). The passage of time is thus largely retrospective now, rather than largely prospective, as it would have been in 1998. Furthermore, it is also undisputed that the petitioner has remained in the food and drug industry for at least a substantial part of that time and has incurred no additional criminal convictions, as acknowledged by ORA. As a result, FDA has more cause to grant the current petition by limiting the period of debarment to less than permanent than the Agency had in 1998, when we denied the previous petition to limit his period of debarment.

Given the foregoing, I have carefully considered the undisputed facts related to the current petition to assess whether granting special termination of debarment would best serve the interest of justice and protect the integrity of the drug approval process in accordance with section 306(d)(4)(C)-(D). I acknowledge that the original conduct that led to his conviction was egregious, as set forth in both the Agency's decision from 1998 and ORA's proposal. Nonetheless, it is in the interest of justice to give great weight to the petitioner's exemplary level of substantial assistance, as is also documented by the Agency's previous decision and

ORA's proposal. Therefore, given the high level of the petitioner's provision of substantial assistance when he cooperated with the Federal government in investigating and prosecuting others for conduct related to the regulation of drugs, as contemplated by section 306(d)(4)(C), FDA has the authority under section 306(d)(4)(D) to limit the period of debarment to a period of at least twenty-eight years because doing so best serves the interest of justice and protects the integrity of the drug approval process.

III. Conclusion

Based on my review of the administrative record, I find that there is no genuine and substantial issue of fact with respect to whether the petitioner provided a qualifying form of substantial assistance or whether granting the current petition would "best serve[] the interest of justice and protect[] the integrity of the drug approval process." Section 306(d)(4)(C)-(D) of the FD&C Act. As the body of this decision explains, because there exists no genuine and substantial issue of fact to resolve at a hearing, I also deny Dr. Kalindindi's request for such a hearing. 21 CFR 16.26(a).

After a consideration of all the undisputed material facts in the administrative record, pursuant to section 306(d) of the FD&C Act, I conclude that granting Dr. Kalidindi's current petition best serves the interest of justice and protects integrity of the drug approval process. Accordingly, I grant Dr. Kalindindi's current petition for special termination of debarment. The agency will publish a notice of this decision in the Federal Register.

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.09.15 15:06:21 -04'00'

RADM Denise M. Hinton
Chief Scientist