practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 pertaining to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03949 Filed 2–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0105]

Shaun Thaxter; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying a request for a hearing submitted by Shaun Thaxter (Thaxter) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Thaxter for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Thaxter was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Thaxter's debarment, FDA has considered the applicable factors listed in the FD&C Act. Thaxter has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable February 27, 2023.

ADDRESSES: Any application for termination of debarment by Thaxter under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2021–N–0105. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act permits FDA to debar an individual if FDA finds that (1) the individual has been convicted of a misdemeanor under Federal law ''for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products'' under the FD&C Act and (2) the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On June 30, 2020, in the U.S. District Court for the Western District of Virginia, Thaxter pled guilty to a misdemeanor violation of the FD&C Act. Specifically, he pled guilty to causing the introduction or delivery for introduction of a misbranded drug into interstate commerce in violation of sections 301(a), 303(a)(1), and 502(a) of the FD&C Act (21 U.S.C. 331(a), 333(a)(1) and 352(a)). In the plea agreement pursuant to which Thaxter pled guilty, he agreed that ''all the facts set forth in the Information [filed by the Federal government on the same day] are true and correct and provide the Court with a sufficient factual basis to support [his] plea.'' The Information provided that, at the time of the conduct underlying his conviction, Thaxter was ''the highest-ranking executive of Reckitt Benckiser Pharmaceuticals Inc. ('RBP').'' [1] During that time, according to the Information, RBP's Medical Affairs Manager provided false or misleading analysis and charts to the Massachusetts Medicaid program (MassHealth), as a means of persuading MassHealth to reimburse patients for a drug named Suboxone Film, which RBP marketed.

As framed by the Information, the false and misleading data and analysis provided to MassHealth—related to the unintended pediatric exposure rates for Suboxone Film relative to similar tablet products—constituted ''labeling'' for the drug under section 201(m) of the FD&C Act (21 U.S.C. 321(m)) and thus misbranded the drug under section 502(a). As discussed further below, in pleading guilty pursuant to the Information, Thaxter conceded that he was a responsible corporate officer at RBP that ''failed to prevent and promptly correct the distribution of [] false and misleading unintended pediatric exposure data and marketing claims to MassHealth'' and ''caused the introduction and delivery for introduction into interstate commerce of . . . a drug [(Suboxone Film)] that was misbranded in that the drug's labeling was false and misleading'' (see *United States* v. *Park,* 421 U.S. 658, 673–74 (1975)). On October 22, 2020, the court entered a criminal judgment against Thaxter and sentenced him to 6 months in Federal prison.

By letter dated March 18, 2021, FDA's Office of Regulatory Affairs (ORA) notified Thaxter of its proposal to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application and provided him with an opportunity to request a hearing on the proposal. ORA found that Thaxter is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act on the basis of his misdemeanor conviction under Federal law for conduct both relating to drug products under the FD&C Act and undermining the Agency's process for regulating drugs. The proposal also outlined findings concerning the factors ORA considered to be applicable in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act. ORA found that a 5-year period of debarment is appropriate. Specifically, ORA found that the nature and seriousness of the offense and the nature and extent of voluntary steps to mitigate the effect on the public are unfavorable factors for Thaxter. ORA stated that it viewed the absence of prior convictions involving matters within FDA's jurisdiction as a favorable factor. ORA concluded that ''the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant the imposition of a five-year period of debarment.''

By letter dated April 28, 2021, through counsel, Thaxter requested a hearing on ORA's proposal to debar him. On May 28, 2021, he submitted a ''Memorandum of Facts and Arguments in Support of Request for Hearing'' (Memorandum). In this Memorandum, Thaxter makes legal, factual, and policy-based arguments regarding the proffered basis for his debarment in ORA's proposal.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Thaxter's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. As discussed in more detail below, hearings will not be granted on issues of policy or law, on mere allegations, on denials or general descriptions of positions and contentions, on data and information insufficient to justify the factual determination urged if accurate and presented at a hearing, or on factual issues that are not determinative with respect to the action requested (see § 12.24(b) (21 CFR 12.24(b))). The Chief Scientist has considered Thaxter's arguments and concluded that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In his Memorandum, Thaxter makes a series of legal and policy arguments challenging whether he is subject to debarment and, if so, whether debarment for 5 years is appropriate. Many of Thaxter's arguments are intertwined with his efforts to raise a genuine and substantial issue of fact with respect to the findings in ORA's proposal to debar him. Thaxter's legal and factual arguments largely turn on the extent to which the specific conduct underlying his conviction subjects him to debarment under section 306(b)(2)(B)(i) of the FD&C Act and the extent to which there are genuine and substantial issues of fact with respect to ORA's findings under section 306(b)(2)(B)(i) and the applicable considerations under section 306(c)(3). In challenging the facts underlying ORA's findings and ultimate debarment proposal, Thaxter contends that some of the findings in ORA's proposal go beyond the facts to which he admitted during the criminal proceedings and are demonstrably false. Specifically, he disputes ORA's proposed findings: (1) that the conduct underlying his conviction put patients and their children at risk, (2) that MassHealth relied on the false and misleading information to expand coverage to include Suboxone Film, and (3) that his conduct exposed patients to misbranded drugs.

In challenging those proposed findings, Thaxter argues extensively that he is entitled to a hearing because not only are there genuine and substantial issues of fact with respect to those findings but they are conclusory and do not appear to rest on substantial evidence. He effectively contends, therefore, that he is entitled to a hearing on those findings for further development and an opportunity to challenge them. However, nothing in

[1] As noted in the Information, ''on or about December 23, 2014, RBP was renamed Indivior, Inc, and became a subsidiary of Indivior PLC. After on or about December 23, 2014, Thaxter was Chief Executive Officer of Indivior PLC.''

the relevant FDA regulations, section 306(i) of the FD&C Act, or the Administrative Procedure Act (APA) requires more than an opportunity to raise genuine and substantial issues of fact with respect to the findings in ORA's proposal. As Thaxter notes, section 306(i) of the FD&C Act requires FDA to provide an ''opportunity for an agency hearing on issues of material fact'' before debarring any person. As noted by ORA in its proposal, FDA implements adjudications required under section 5 U.S.C. 554(a), including debarment matters, as formal evidentiary hearings under 21 CFR part 12.

Under § 12.24(b), consistent with the APA and case law, there are criteria for granting a hearing. Pursuant to that regulation, the Agency will grant a request for hearing only if the material submitted in support of the hearing request shows, in relevant part: (1) ''[t]here is a genuine and substantial factual issue for resolution at a hearing,'' (2) ''[t]he factual issue can be resolved by available and specifically identified reliable evidence,'' (3) ''[t]he data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person,'' and (4) ''[r]esolution of the factual issue in the way sought by the person is adequate to justify the action requested.'' The regulation further clarifies that ''[a] hearing will not be granted on issues of policy or law'' and that ''a hearing will not be granted on factual issues that are not determinative with respect to the action requested.''

The factual challenges in Thaxter's Memorandum do not justify granting his hearing request. Even Thaxter himself does not dispute the facts to which he pled guilty. Rather, Thaxter attempts to show that those undisputed facts do not support ORA's proposed findings. Specifically, Thaxter argues that only disputed facts could plausibly support a finding that his conduct harmed children or patients or that MassHealth actually relied on the false and misleading information in making its ultimate decision to add Suboxone Film to its formulary. Thaxter appears to acknowledge, as he must, that the facts to which he pled guilty—*i.e.,* the findings of the court that entered a criminal judgment against him—are not in dispute. In addition, he does not contest several other discrete findings in ORA's proposal. For reasons discussed in detail below, it is not necessary to go beyond the facts to which Thaxter pled guilty and the other undisputed facts in ORA's proposal to conclude that Thaxter is subject to debarment under section 306(b)(2)(B)(i) of the FD&C Act and that debarment for 5 years is appropriate under section 306(c)(3).

For the sake of simplicity and efficiency, what follows is an assessment of the remainder of Thaxter's legal, factual, and policy-based arguments by reference only to the facts to which he pled guilty or the other undisputed findings in ORA's proposal. Consequently, the Chief Scientist need not further address Thaxter's arguments regarding the accuracy of ORA's findings regarding whether the conduct underlying his conviction exposed patients or their children to risk and misbranded drugs or caused MassHealth to rely on the false and misleading information.

A. Thaxter Is Subject to Debarment

Thaxter argues that he is not subject to debarment under section 306(b)(2)(B)(i) of the FD&C Act because the conduct to which he pled guilty did not ''undermine[ ] the process for the regulation of drugs'' in the sense contemplated by that statutory provision:

> To issue a final order of debarment, 21 U.S.C. 335a requires a finding by the Secretary [under section 335a(b)(2)(B)] that ''the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.'' . . . This phrase is not defined in the statute. But the statute's structure and purpose, legislative history, and FDA's own precedent make clear that the statute is intended to reach individuals and entities that either: (1) engage in conduct that undermines the development or approval process itself; or (2) engage in significant fraud or blameworthy behavior such that the extraordinary remedy of debarment would be appropriate to prevent that person from even indirectly participating in the process of drug approval and regulation.

In addition to raising constitutional issues regarding any contrary construction of section 335a(b)(2)(B), discussed in more detail below, he maintains, ''There is no reason to conclude that Congress intended FDA to impose the draconian debarment sanction for infractions that do not significantly undermine the regulatory process.'' Thaxter further argues that his criminal conduct lacks a sufficient nexus to ''the regulation of drug products'' under the FD&C Act and did not include sufficiently fraudulent or blameworthy behavior to warrant debarment if such conduct did not relate to the development or approval process for drugs:

> [His] conviction is not related to the development or approval process itself, and the conviction as described in the Information is not sufficiently severe standing alone to call into question the integrity of the process for review and approval of drug products such that it would warrant debarment as contemplated by the drafters of the statute. [He] had no bad intent and no contemporaneous knowledge of the underlying 2012 misstatements by an employee who did not report to him directly. When he learned about the misstatements in 2015—more than two years after they were made—he directed their correction. He engaged in no fraud or dishonesty, and he was not required to pay any restitution to MassHealth or any other entity. His crime was being in a position of authority at [RBP] and failing to prevent a subordinate employee who did not report to him directly from sending inaccurate data about Suboxone [Film] to a MassHealth official. It had nothing at all to do with the development or approval process of Suboxone, and it did not involve fraud, bribery, or obstruction of justice, or anything else to support a conclusion that he cannot be trusted to participate in the pharmaceutical industry.

In support of these arguments, Thaxter points to the legislative history of section 306 of the FD&C Act and contends further that FDA's own public statements during the legislative process ''demonstrate how the debarment authority was primarily concerned with addressing significant fraud and misconduct within the development or approval process for drugs.'' Section 306(b)(2)(B)(i) of the FD&C Act, however, specifically provides for debarring individuals convicted of Federal misdemeanors related to the regulation of drug products. If the language of the statute is clear, there is no need to look outside the statute to its legislative history to ascertain the statute's meaning (*Chamber of Commerce of United States* v. *Whiting* 63 U.S. 582, 599 (2011)). Furthermore, 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. When 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)).

Thaxter's further argument that he is not subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act because he pled guilty to a Federal misdemeanor offense without admitting any intent to violate the law or knowledge of wrongdoing is also unavailing. Given that section 306(b)(2)(B)(i) explicitly permits debarring individuals convicted of Federal misdemeanors related to the regulation of drug products and that a misdemeanor violation of the FD&C Act itself is a strict liability offense under

section 303(a)(1), it stands to reason that criminal intent is not required to subject an individual to debarment under section 306(b)(2)(B)(i)(I). In this case, however, Thaxter's guilty plea was not based on strict liability or ''pure, vicarious liability,'' as he argues. As highlighted in ORA's proposal, his conviction was based on his failure to prevent RBC ''from sending false and misleading information to MassHealth related to the relative rate of unintended pediatric exposures of Suboxone Film'' and ''to promptly correct that information once it was provided.'' Indeed, the Information to which Thaxter pled guilty provided that he, ''as a responsible [RBP] executive failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth'' and that, accordingly, he caused the introduction and delivery for introduction of a misbranded drug into interstate commerce. He cannot now hide behind his arguments that he lacked specific knowledge that the labeling for the Suboxone Film was false and misleading in attempting to overcome the debarment resulting from the facts admitted to as part of his plea agreement. As the Supreme Court has reasoned, in keeping with the FD&C Act's purpose of protecting the public from adulterated and misbranded products, Congress chose to place the burden of protecting the public on those who play a role in manufacturing and distributing those products rather than on consumers, who cannot protect themselves (*United States* v. *Dotterweich,* 320 U.S. 277, 280–81 (1943)). The duty imposed on responsible corporate officers (RCOs) ''requires the highest standard of foresight and vigilance'':

> The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them (*Park,* 421 U.S. at 672–73).

Nor are Thaxter's arguments that his conduct underlying his conviction ''lack[ed] the required nexus to the 'process for the regulation of drugs'" to subject him to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act availing. Simply put, he pled guilty to causing the introduction of a misbranded drug into interstate commerce *in violation of the FD&C Act* (specifically, sections 301(a), 303(a)(1), and 502(a) of the FD&C Act). In section 306(b)(2)(B)(i)(I), ''a misdemeanor under Federal law or a felony under State law for conduct . . . otherwise relating to the regulation of drug products'' subjects an individual to permissive debarment. There are no genuine and substantial issues of fact regarding whether Thaxter pled guilty to—and therefore committed—a misdemeanor under Federal law. When that Federal misdemeanor is for conduct that directly violated the FD&C Act with respect to drug labeling, there is no question that such violation relates to the regulation of drugs under that statutory authority.

Thaxter makes many similar arguments with respect to whether the conduct to which he pled guilty as part of his misdemeanor plea is ''the type of conduct [that] . . . undermines the process for the regulation of drugs'' under the FD&C Act in the sense contemplated by section 306(b)(2)(B)(i)(I) of the FD&C Act. In doing so, he attempts to distinguish between conduct relating to the development and approval process for drug products and conduct relating to other aspects of drug regulation under the FD&C Act. Although he supports that distinction by pointing to the legislative history of section 306 and offering policy arguments, neither section 306(b)(2)(B)(i)(I) nor the FD&C Act as a whole bear out that distinction. The plain language of section 306(b)(2)(B)(i)(I) does not draw the distinction urged by Thaxter and indeed expands the scope of the statutory provision beyond conduct relating to the development and approval process by including the language ''otherwise relating to the regulation of drug products.'' With respect to the purpose of FD&C Act as a whole, the Supreme Court has found that its aims go well beyond the development and approval process for drug products: ''Its purpose [is] to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer'' (*United States* v. *Sullivan,* 332 U.S. 689, 696 (1948)).

Thaxter nonetheless argues that the ''underlying facts of [his] plea only demonstrate[] a 'technical' misbranding'' and that thus his conduct did not undermine the process for the regulation of drugs. As ORA correctly determined, however, his conduct went beyond a mere technical violation of the FD&C Act. Thaxter's conduct included providing inaccurate information about a drug product to a State health agency focused on the safety profile of the drug at issue:

> [Thaxter's] actions undermined the process for the regulation of drugs because [he] failed to prevent [RBP] from sending false and misleading data and information to MassHealth related to the rate of unintended pediatric exposure to Suboxone Film[] and did not promptly correct such information and data.

Notwithstanding Thaxter's assertions to the contrary, an important and fundamental objective of the FD&C Act is preventing the labeling of a drug product from containing false and misleading information about the product's safety profile.[2] The type of conduct to which Thaxter pled guilty did undermine the process for the regulation of drugs in the sense contemplated by both section 306(b)(2)(B)(i)(I) and the FD&C Act as a whole.

In light of the foregoing, the Chief Scientist finds that Thaxter has failed to raise a genuine and substantial issue of fact with respect to (1) whether the conduct serving as the basis of his Federal misdemeanor conviction related to the regulation of drugs and is the type of conduct that undermines the process for the regulation of drugs and thus (2) whether he is subject to debarment under the terms of section 306(b)(2)(B)(i)(I) of the FD&C Act.

B. Appropriateness of a 5-Year Debarment Period

In support of his hearing request, Thaxter further argues in his Memorandum that he is entitled to a hearing on ORA's findings with respect to the considerations in section 306(c)(3) of the FD&C Act. He contends both that ORA erred in considering only three of the six factors in section 306(c)(3) and that there are genuine and substantial issues of fact with respect to five of the six factors. With respect to the sixth factor, which concerns whether a person subject to debarment has prior convictions under the FD&C Act or for offenses for matters within the jurisdiction of FDA, Thaxter argues that ORA ''failed to afford any weight the fact that [he] has no prior convictions.''

Thaxter's argument that the Agency must consider all six factors in section 306(c)(3) of the FD&C Act in determining the appropriateness and period of his debarment under section 306(b)(2)(B)(i)(I) is belied by the language of the statute. FDA need only address the considerations in section

[2] In fact, as has already been discussed at length, Thaxter admitted that the conduct in question—for which he admitted responsibility as an RCO—misbranded a drug product while in the very chain of commerce that the Supreme Court has said the FD&C Act is intended to safeguard in order to protect the consumer (see *Sullivan,* 332 U.S. at 696).

306(c)(3) ''where applicable.'' The considerations in section 306(c)(3) apply not only to individuals but also to corporations, partnerships, and associations subject to permissive debarment under section 306(b)(2) and (3). Thus not all aspects of the considerations are necessarily applicable in every case.

In his Memorandum, Thaxter specifically points to the considerations in section 306(c)(3) of the FD&C Act on which ORA made no findings in its proposal, specifically paragraphs (B), (D), and (E). Paragraphs (D) and (E) are not applicable to Thaxter based on the undisputed record before FDA. Under section 306(c)(3)(D), FDA must, ''where applicable,'' consider ''whether the extent to which changes in ownership, management or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future.'' Under 306(c)(3)(E), the Agency must, again ''where applicable,'' consider ''whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated new drug applications [ANDAs] and all pending [ANDAs] are free of fraud and material false statements.''

Those two considerations are rarely, if ever, applicable to an individual, particularly one that is no longer employed by the business entity where that individual committed the offenses at issue, as is the case here. Whether it is appropriate to debar an individual as a remedial measure to protect the integrity of the process for regulating drugs and, if so, for how long, turns on an assessment of the individual in light of the conduct underlying the offense and other factors related to the individual. The applicable considerations for individuals under section 306(c)(3) of the FD&C Act thus do not typically hinge on corrective actions at a corporation or any other efforts made by that corporation to prevent the promulgation of fraud or materially false statements.

The focus under section 306(c)(3)(D) of the FD&C Act is on whether there have been changes in ownership, management, or operations that might provide assurances that the offense at issue will not occur again. This consideration could only be meaningful to assessing the appropriateness and period of debarment for an individual if those changes occurred at a business enterprise in which the individual is currently engaged and the individual could not acquire a position elsewhere in the drug industry absent debarment. Furthermore, not only does Thaxter attempt to expand the scope of section 306(c)(3)(E) to include measures taken to prevent the promulgation of fraud or materially false information beyond those relating to ANDAs, he relies on the steps taken by another person: Invidior PLC (Invidior), a successor corporation to RBP for which he also served as Chief Executive Officer. Nonetheless, insofar as Thaxter describes evidence or raises facts about corrective actions at RBP's successor company, Invidior, the Chief Scientist evaluates those proffered facts and arguments in the context of the consideration regarding ''voluntary steps'' in section 306(c)(3)(C), which is applicable to individuals.

In his Memorandum, as noted above, Thaxter argues that ORA's proposal to debar him for 5 years ignored the consideration in section 306(c)(3)(B) of the FD&C Act, namely ''the nature and extent of management participation in any offense involved, whether corporate policies encouraged the offense, including whether inadequate institutional controls contributed the offense.'' He contends that the Agency should grant ''a hearing to ensure this factor is afforded proper weight in FDA's consideration of the [section 306(c)(3)] factors.'' In support of this position, Thaxter points to his motivations, as the highest-ranking executive officer at RBP, to encourage the truthful promotion of Suboxone Film and other buprenorphine-containing products and to prevent abuse and diversion, and he lists a series of company policies, initiatives, and communications in which he claims to have had a hand in issuing or developing.

In contrast to the considerations in paragraphs (D) and (E) of section 306(c)(3) of the FD&C Act, the Agency has often considered the factor in subparagraph (B) in assessing the appropriateness and period of debarment for individuals under section 306(b)(2)(B)(i)(I) of the FD&C Act (see, *e.g.,* ''Dilip Patel; Denial of Hearing; Final Debarment Order'' (83 FR 48829 at 48830, September 27, 2018)). The record before FDA does not disclose why ORA did not find that consideration to be applicable here, and the proposal does not cite the consideration as either a favorable or unfavorable factor. Even if the Agency were to consider the factor in section 306(c)(3)(B) in assessing the appropriateness and period of Thaxter' debarment in light of the additional policies, initiatives, and communications described by him in his Memorandum, that factor would not be favorable.

As discussed above in relation to whether conduct underlying Thaxter's conviction was sufficiently serious to warrant debarment, and as highlighted in ORA's proposal, Thaxter admitted during his criminal proceedings that he was an RCO with authority to either prevent in the first instance or to promptly correct the provision of false and misleading information to MassHealth and that he took neither action. By admitting such authority and responsibility, Thaxter conceded both that he served in a managerial role for the offense involved and that the ''corporate policies and practices'' to which he points—many of which do not directly relate to the offense to which he pled guilty—were inadequate to prevent that offense. Indeed, the essence of his guilty plea as an RCO is that he failed to fulfill the duties imposed on him by the FD&C Act by having the policies and practices in place (including his own, as an individual RCO) to prevent the offense at issue. Given that the consideration in section 306(c)(3)(B) of the FD&C Act would not be favorable to Thaxter, even assuming the accuracy of the additional information provided by him, the Chief Scientist, like ORA, will not treat this consideration as either favorable or unfavorable.

With respect to the three considerations under section 306(c)(3) of the FD&C Act on which ORA made factual findings in its proposal to debar him, Thaxter disputes the factual basis for two of them and argues that ORA's proposal gives insufficient weight to the third. After separately evaluating the arguments with respect to the factual basis for two of the considerations—specifically, those under paragraphs (A) and (C)—the Chief Scientist assesses whether, taken together, the three considerations warrant debarment for 5 years, including the weight to be given the third under subparagraph (F).

Thaxter first argues that ORA's assessment of the nature and seriousness of his offense under section 306(c)(3)(A) is flawed: (1) because ORA erroneously relied on the premise that his criminal conduct ''put children at risk,'' and (2) because ''failing to prevent a subordinate employee from providing misleading information to a state Medicaid official more than eight years ago'' is not sufficiently serious or recent enough to warrant a 5-year debarment period, especially without a showing that such conduct resulted in ''drugs being tainted or counterfeited'' or ''patient care [being] compromised.'' It is not necessary to go beyond the facts to which Thaxter pled guilty to resolve the additional factual issues to which Thaxter now points. Whether Thaxter's

conduct ''put children at risk'' or compromised patient care is not determinative with respect to the appropriateness of debarring him for 5 years. It is also not necessary to reach whether his conduct caused drug products to be tainted or counterfeited.

Notwithstanding Thaxter's assertions to the contrary, as ORA found and has been discussed at length above, Thaxter took responsibility for RBP's introducing, and delivering for introduction, a misbranded drug into interstate commerce. He admitted as part of his guilty plea that he was in a position both to prevent the violations resulting from his subordinate's conduct—*i.e.,* the inclusion of false and misleading information in the labeling for Subluxone Film—or to correct them promptly. But he did not. Building on the reasoning above with respect to whether the type of conduct serving as the basis of Thaxter's misdemeanor conviction undermined the process for the regulation of drugs, the Chief Scientist finds that Thaxter's role and responsibility in the introduction of a drug whose labeling and false and misleading under section 502(a) of the FD&C Act—especially when the labeling at issue went directly to a State Medicaid agency and when viewed within the range of potential misdemeanor convictions that might subject an individual to permissive debarment under section 306(b)(2)(B)(i)(I)—is sufficiently serious to warrant treatment as an unfavorable factor. In short, Thaxter has failed to raise a genuine and substantial issue of fact with respect to ORA's findings regarding the nature and seriousness of his offense under section 306(c)(3)(A).

Thaxter next argues that, in evaluating ''the nature and extent of voluntary steps to mitigate the impact of any offense involved'' under section 306(c)(3)(C) of the FD&C Act, ORA did not fully consider his role in authorizing ''a disclosure to MassHealth alerting it to the misinformation sent previously.'' He takes issue with ORA's suggestion that ''the delay in sending the correction letter—which was not [his] fault . . . since he had no knowledge of the underlying conduct at the time—justifies discounting the weight of the corrective letter that [he] directed the Company to send promptly after he learned of the events at issue.'' Again, however, the facts to which Thaxter pled guilty belie this assertion. As part of his guilty plea, he admitted that he was an RCO ''with authority to either prevent in the first instance or to promptly correct the provision of false and misleading information to MassHealth and that he took neither action.'' He cannot now claim that his corrective action was prompt, and he does not dispute that he directed the correction ''only after an investigation was opened into this matter.''

Thaxter further maintains that, in light of the eventual corrective action directed by him, ORA's conclusion that he failed to ''take *any* steps to mitigate the potential impact on the public (emphasis Thaxter's)'' is unfounded. But neither ORA's evaluation of this consideration as a whole in the proposal nor the Chief Scientist's evaluation hinges to any meaningful degree on the omission of the word ''prompt'' in ORA's conclusion to that effect. Furthermore, although Thaxter argues that ''a hearing is needed to clarify the steps [he] took after he learned of the misstatement and the corrective action he directed the Company to take,'' he does not provide sufficient detail regarding ''voluntary steps'' under section 306(c)(3)(C) to deduce what those steps were and thus fails to present a material factual issue with respect to those steps to be resolved at a hearing.

Insofar as Thaxter points to additional, specific corrective actions, he does so in his arguments regarding paragraphs (D) and (E) of section 306(c)(3) of the FD&C Act in regard to the actions of Invidior, as noted above. With respect to whether changes in operations at Invidior have corrected the cause of his own misdemeanor offense, he points to a Corporate Integrity Agreement with the Office of Inspector General in the Department of Health and Human Services (CIA) into which the company entered as part of a comprehensive settlement agreement. However, Thaxter fails to point to any role he might have had in that CIA as an individual. Thaxter's arguments regarding the CIA's requirement that Invidior adopt ''detailed and state-of-the-art compliance measures'' to ensure that the manufacture and sale of its drug products remain free of fraud and materially false statement must fail on analogous reasoning. Accordingly, the Chief Scientist finds that Thaxter has failed to raise a genuine and substantial issue of fact with respect to ORA's findings regarding the voluntary steps taken by him to mitigate the effect of his offense on the public under section 306(c)(3)(C).

Based on the undisputed record before FDA, primarily encompassing the facts to which Thaxter pled guilty, the Chief Scientist finds that a 5-year debarment is appropriate. Although Thaxter has no previous criminal convictions related to matters within the jurisdiction of FDA, this sole favorable factor does not counterbalance the nature and seriousness of his offense and lack of voluntary steps promptly taken to mitigate the effect of that offense on the public. As has been discussed at length, Thaxter admitted as part of his guilty plea that, as an RCO, he possessed the authority, opportunity, and responsibility to prevent or promptly correct conduct that caused false and misleading information to go to a State Medicaid agency and thereby caused the introduction of a misbranded drug into interstate commerce. His failure to prevent or promptly correct conduct breached the fundamental responsibility as an RCO when he voluntarily assumed a ''position[ ] of authority in [a] business enterprise[ ] whose services and products affect the health and well-being of the public'' (*Park,* 421 U.S. at 573). In short, the Chief Scientist agrees with ORA's conclusion in its proposal that ''the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant the imposition of a five-year period of debarment.''

C. Remaining Legal Arguments

In addition to the foregoing arguments regarding the statutory and factual basis for his debarment, Thaxter argues that debarring him ''for a non-intent, strict liability misdemeanor, without any assessment of underlying knowledge or lack of participation in the conduct of the offense'' would violate ''both his procedural and substantive due process rights'' under the Fifth Amendment, given the liberty and property interests at stake. He claims a lack of notice that he could be subject to debarment for conduct as an RCO. Relying on *Morissette* v. *United States,* 342 U.S. 246, 256 (1952), he also argues that the effect debarment will have on his employment opportunities in his chosen profession and his reputation go beyond the effects of a misdemeanor conviction contemplated by the Supreme Court in that case.

As is extensively discussed above, however, Thaxter did not plead guilty based purely on strict liability. He admitted as part of his guilty plea that he was an RCO ''with authority to either prevent in the first instance or to promptly correct the provision of false and misleading information to MassHealth and that he took neither action.'' (see *Park,* 421 U.S. at 673–74). As discussed above, under the terms of section 306(b)(2)(B)(i)(I) of the FD&C Act, he is subject to permissive debarment for up to 5 years based on the Federal misdemeanor to which he pled guilty.

The FD&C Act itself provides for misdemeanor liability under section 303(a)(1). Taken together, section 306(b)(2)(B)(i)(I) and (c)(3) prescribes the circumstances under which the Agency will exercise its discretion to debar individuals convicted of misdemeanors under the FD&C Act. Furthermore, in this case, the Agency has made the appropriate findings and considered the proper statutory criteria in evaluating the appropriateness and period of Thaxter's debarment. Accordingly, the Chief Scientist does not agree that Thaxter's debarment for 5 years violates his right to due process.

Thaxter next argues that debarring him for 5 years would be ''unreasonable and would not comport with the basic requirements of reasoned decision-making'' unless FDA were to justify ''the radical departure from precedent that debarring [him] would represent.'' He argues further that ''it would be arbitrary, capricious, and contrary to law for FDA to [debar] a party that has not taken action that poses a significant threat to the integrity of the regulatory system'' or ''not to hold a hearing to support its position.''

Based on Thaxter's arguments and the case law he cites, he appears to be relying on the judicial standard for review of Agency decision-making in the APA at 5 U.S.C. 706(2), which directs courts to ''hold unlawful and set aside agency action[s]'' that are ''arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'' As the Supreme Court has held, the question under that standard is whether the Agency has provided a reasonable explanation for the substance its decision:

> The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. Judicial review under that standard is deferential, and a court may not substitute its own policy judgment for that of the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision (*FCC* v. *Prometheus Radio Project,* 141 S. Ct. 1150, 1158, 209 L. Ed. 2d 287 (2021)).

In this matter, as reflected in the lengthy discussion above, the Agency has reasonably considered the relevant issues and fully explained its decision to debar Thaxter. Although Thaxter points to other individuals who pled guilty to misdemeanors based on liability as RCOs and who have not been debarred, he provides no details with respect to those individuals' convictions. Even assuming, however, that those individuals were similarly situated to him, his bare assertion that an Agency cannot choose to begin pursuing debarment of individuals for certain discrete categories of Federal misdemeanor convictions because it has not done so in the past is unfounded. As discussed, the terms of section 306(b)(2)(B)(i)(I) and (c)(3) of the FD&C Act are clear, and the Agency has exercised its discretion here in a manner consistent with the permissive debarment of many other individuals convicted of Federal misdemeanors. Accordingly, Thaxter's argument that debarring him is arbitrary, capricious, and contrary to law lacks merit.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to her by the Commissioner of Food and Drugs, finds that (1) Thaxter has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Thaxter is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 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), effective (see **DATES**) (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Thaxter, 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 Thaxter, during his period of debarment, 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 Thaxter during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 21, 2023.

Namandjé N. Bumpus,

Chief Scientist.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1046]

Wojciech Lesniak: Final Debarment Order

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 (FD&C Act) debarring Wojciech Lesniak for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lesniak engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Mr. Lesniak was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of November 21, 2022 (30 days after receipt of the notice), Mr. Lesniak had not responded. Mr. Lesniak's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable February 27, 2023.

ADDRESSES: Any application by Mr. Lesniak for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or