actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, LOKELMA (sodium zirconium cyclosilicate). LOKELMA is indicated for the treatment of hyperkalemia in adults. Subsequent to this approval, the USPTO received patent term restoration applications for LOKELMA (U.S. Patent Nos. 8,802,152 and 8,808,750) from ZS Pharma Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LOKELMA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LOKELMA is 2,384 days. Of this time, 1,295 days occurred during the testing phase of the regulatory review period, while 1,089 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 9, 2011. The applicant claims September 11, 2011, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 9, 2011, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 26, 2015. The applicant claims May 25, 2015, as the date the new drug application (NDA) for LOKELMA (NDA 207078) was initially submitted. However, FDA records indicate that NDA 207078 was submitted on May 26, 2015.

3. *The date the application was approved:* May 18, 2018. FDA has verified the applicant's claim that NDA 207078 was approved on May 18, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 29 days or 98 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02667 Filed 2–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1996]

Hassan Tahsildar; 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 Hassan Tahsildar's (Dr. Tahsildar's) request for a hearing and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Tahsildar for 2 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 Dr. Tahsildar was convicted of a misdemeanor under Federal law for causing the introduction or delivery for introduction of misbranded drugs into interstate commerce. Additionally, FDA finds that the conduct underlying Dr. Tahsildar's conviction related to the regulation of drugs under the FD&C Act and that the type of conduct underlying his conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Tahsildar's debarment, FDA considered the relevant factors listed in the FD&C Act and concluded that a hearing is unnecessary.

DATES: This order is applicable February 8, 2023.

ADDRESSES: Any application for termination of debarment by Dr. Tahsildar 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–2018–N–1996. 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 regulation of drug products under the FD&C Act, and (2) the type of conduct underlying the conviction undermines the process for the regulation of drugs.

On September 30, 2013, Dr. Tahsildar pled guilty to a misdemeanor for introducing, or causing the introduction of, a misbranded drug into interstate commerce, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)). According to the criminal information to which Dr. Tahsildar pled guilty, between January 10, 2006, and March 12, 2009, Dr. Tahsildar ''purchased and received'' prescription oncology drugs from Canada. In pleading guilty, Dr. Tahsildar's admitted that his actions caused the introduction into interstate commerce of drugs that were misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) because their labeling did not bear adequate directions for use. On January 28, 2014, the U.S. District Court for the Northern District of Ohio entered a judgment of conviction against Dr. Tahsildar for his violation of section 301(a) of the FD&C Act and sentenced him to 1 year of probation.

By letter dated July 13, 2018, FDA's Office of Regulatory Affairs (ORA) proposed to debar Dr. Tahsildar for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal explained that ORA based the proposed debarment on his misdemeanor conviction and concluded that a 3-year debarment is appropriate.

By letter dated September 10, 2018, Dr. Tahsildar, through counsel, requested a hearing on the proposal. Dr. Tahsildar argues that there are genuine and substantial issues of fact that support his request for a hearing. He contends that, in contrast to the findings in ORA's proposal to debar him, he did not receive notices from FDA that certain drugs being shipped from Canada to the medical practice in which he was a partner had been detained on the ground that they appeared to be unapproved drugs. He also asserts that he was never involved in the management or daily operations of the medical practice in which he was a ''junior partner,'' including contracting with drug suppliers or ordering drugs for use in the practice.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Dr. Tahsildar's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

The Chief Scientist has considered Dr. Tahsildar's arguments, as well as the proposal to debar, and concludes that there is no genuine and substantial issue of fact requiring a hearing.

II. Arguments

In response to the proposal to debar, Dr. Tahsildar does not appear to challenge that he is subject to debarment under section 306(b)(2)(B) of the FD&C Act. Instead, Dr. Tahsildar disputes the factual basis for ORA's findings with respect to the considerations under section 306(c)(3) of the FD&C Act. ORA's proposal outlined findings concerning the four factors that ORA considered in determining the appropriateness and period of debarment: (1) the nature and seriousness of the offense, (2) the nature and extent of management participation in the offense, (3) the nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the FD&C Act or other acts involving matters within FDA's jurisdiction. ORA found that the first two factors were unfavorable factors and that the latter two factors were favorable for Dr. Tahsildar. The proposal concluded that the unfavorable factors outweigh the favorable factors and that a 3-year debarment is thus appropriate.

With respect to the nature and seriousness of his offense under section 306(c)(3)(A) of the FD&C Act, ORA found in the proposal that the conduct underlying Dr. Tahsildar's misdemeanor conviction included ''purchasing and receiving numerous units of unapproved oncology drugs . . . from a Canadian distributor.'' ORA further found that Dr. Tahsildar ''continued purchasing these drugs despite being notified by FDA on multiple occasions that foreign drug shipments destined for [his] office had been detained and appeared to be unlawfully marketed unapproved new drugs.'' Relying on those factual findings, ORA determined that his conduct ''created a risk of injury to consumers'' and ''undermined the

Agency's drug approval process and the Agency's oversight of the manufacture, importation, and sale of drug products in interstate commerce in the United States.''

In support of his hearing request, Dr. Tahsildar maintains not only that he had ''no intention of violating the law'' but also that ''he had no prior knowledge that any of the medications coming into his practice were imported from Canada.'' He explains that he first learned that the practice's Texas supplier had been ''shipping Canadian drugs to the practice'' when two agents from FDA visited the practice and provided that information to him, at which point the practice severed its relationship with the Texas supplier and ''never received medications from Canada or the Texas supplier again.'' Indeed, he specifically challenges as inaccurate ORA's finding that ''he continued purchasing [the] drugs despite being notified by FDA on multiple occasions that foreign drug shipments destined for [his] office had been detained and appeared to be unlawfully marketed unapproved new drugs'' :

> Please note that there is an inaccuracy in [ORA's proposal.] Dr. Tahsildar did not continue to purchase the Canadian drugs and was not notified by the FDA on multiple occasions that foreign drug shipments destined for his office had been detained and appeared to be unlawfully marketed unapproved new drugs. I believe [ORA is] referring to the four notices from the FDA with status dates of May 2, June 27, October 21, and November 17, 2008. All such notices were addressed to [his partner] and were not brought to Dr. Tahsildar's attention until after the two FDA agents came to the office in 2009.

He further points to the findings of the State Medical Board of Ohio in support of these assertions. As quoted by Dr. Tahsildar, the State Medical Board determined that ''[r]eprints of FDA detainer notices . . . clearly show that they had been addressed to'' his partner.

Insofar as Dr. Tahsildar argues that he did not intend to violate the FD&C Act, he has not raised a genuine and substantial issue of fact with respect to the nature and seriousness of his misdemeanor offense. A misdemeanor violation of the FD&C Act itself is a strict liability offense under section 303(a)(1) of the FD&C Act (21 U.S.C. 333(a)(1)) and requires no showing of any criminal intent, and his mere assertion that he lacked any intent to violate the law is of no moment whatsoever. On the other hand, the Chief Scientist need not address whether Dr. Tahsildar's factual challenges to ORA's key finding that he continued to order the oncology drugs at issue after FDA provided him notice that they were unapproved and thus violated the FD&C Act raise a genuine and substantial issue of fact with respect to that finding because the Chief Scientist will assume for purposes of determining the appropriateness and period of his debarment that he received no such notice and that the medical practice discontinued ordering such drugs after he learned they were unapproved.

With respect to ORA's findings as to the nature and seriousness of his offense under section 306(c)(3)(A) of the FD&C Act, Dr. Tahsildar also challenges ORA's finding that the conduct underlying his misdemeanor offense ''created a risk of injury to consumers.'' Dr. Tahsildar contends that Federal prosecutors ''made no allegations whatsoever that [he] engaged in any conduct that put his patients at risk'' and that ''the FDA agents [who visited the practice] told him that the FDA was not concerned that drugs at issue were inferior'' and that the practice could continue using the drugs. This factual challenge does not raise a genuine and substantial issue of fact. Violating the FD&C Act in a manner that results in administering unapproved drugs to patients creates an inherent risk to those patients, notwithstanding any alleged statements to the contrary by FDA agents or the failure of Federal prosecutors to rely on those facts as part of the criminal prosecution.

Dr. Tahsildar next challenges ORA's findings regarding nature and extent of his management participation under section 306(c)(3)(B) of the FD&C Act. In its proposal, ORA stated that, as a licensed physician, Dr. Tahsildar ''held a position of authority in [his] medical practice where [his] conduct served as an example for his employees.'' ORA found that his conduct was more serious than if he were a mere employee and found this factor to be unfavorable for Dr. Tahsildar.

In response to these findings, Dr. Tahsildar states that ''he was never involved in the management or daily operations of the practice, including contracting with medication suppliers or ordering any medications'' :

> When [he] was hired by [the senior partner] in 1995, he was a first-time practicing physician, coming directly out of fellowship. In 1998, Dr. Tahsildar became a junior partner of [the] practice. [The senior partner] retained a 51% ownership interest in the practice, and Dr. Tahsildar purchased a 49% ownership interest. [The senior partner] remained in control of the management and day-to-day operations of the practice, giving no control to Dr. Tahsildar. This [arrangement], however, worked well for Dr. Tahsildar because he had wanted to remain a clinician only and had been happy to leave the management and financial aspects of the practice to [the senior partner], who in turn received a three[-]percent management fee for doing so. Dr. Tahsildar received no such management fee.

Dr. Tahsildar further contends that he ''did not negotiate or sign contracts on behalf of the practice (including any medication supplier contracts), nor did he sign checks on behalf of the practice, with the exception of one occasion.'' He also maintains that he was never involved in ordering any drugs for the medical practice. Dr. Tahsildar argues, therefore, that the Agency should consider his management participation in the offense under section 306(c)(3)(B) of the FD&C Act as a favorable factor.

As a preliminary matter, the Chief Scientist notes that Dr. Tahsildar admitted during the criminal proceedings against him that he ''purchased and received'' the oncology drugs at issue when he pled guilty pursuant to a criminal information charging him with that conduct. His assertions to the contrary do not raise a genuine and substantial issue of fact. Nevertheless, his contentions regarding his role in the practice, though not in direct conflict with the findings in ORA's proposal, do provide additional factual context for ORA's findings and thus warrant consideration under section 306(c)(3)(B) of the FD&C Act. However, notwithstanding Dr. Tahsildar's claims that he did not take an active role in managing the practice, including ordering drug products, it is undisputed that Dr. Tahsildar was in a position of authority in the practice, even if he was not the managerial equal to the senior partner. By his own admission, Dr. Tahsildar was one of two partners in a medical practice, and he failed to ensure that his patients were receiving FDA-approved drugs. The Chief Scientist will nonetheless account for Dr. Tahsildar's provision of additional factual context regarding his role in the practice in assessing the consideration under section under 306(c)(3)(B) of the FD&C Act in determining the appropriateness and period of his debarment, as discussed below.

Considering all the applicable factors listed in section 306(c)(3) of the FD&C Act, the Chief Scientist finds that Dr. Tahsildar's misdemeanor offense and underlying conduct warrant a 2-year debarment period, as opposed to the 3-year period of debarment proposed by ORA. Although the Chief Scientist has assumed that Dr. Tahsildar had no prior

notice that the oncology drugs at issue were unapproved and that the medical practice discontinued ordering those drugs when he learned of that regulatory status, as discussed above, it is undisputed that the offense to which he pled guilty led to his administering foreign, unapproved drug products to his patients. Even assuming Dr. Tahsildar's representations with respect to his reduced role as a manager in the practice to be true, the Chief Scientist also cannot conclude that his managerial role is a favorable consideration, given his status as a partner and a physician in that practice. Balancing the applicable considerations—including his voluntary steps in mitigation under section 306(c)(3)(C) of the FD&C Act and the absence of previous criminal convictions related to matters within the jurisdiction of FDA under section 306(c)(3)(F)—the Chief Scientist has determined that a 2-year debarment period is appropriate. Inasmuch as there are no material factual disputes for resolution at a hearing, the Chief Scientist is also denying Dr. Tahsildar's hearing request.

Separately, Dr. Tahsildar requests that, in lieu of debarment by FDA, he enter into a settlement agreement with FDA whereby he would voluntarily agree to the terms of the proposed debarment for the proposed period of debarment and to not provide services in any capacity to a person that has an approved or pending drug product application. Dr. Tahsildar appears to be proposing an informal resolution of this debarment matter. However, his request is now moot given that the foregoing findings support debarment for a 2-year period.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and authority delegated to her by the Commissioner of Food and Drugs, finds that Dr. Tahsildar has been convicted of a misdemeanor under Federal law for conduct related to the regulation of drugs under the FD&C Act and that the type of conduct underlying the conviction undermines the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a 2-year debarment is appropriate.

As a result of the foregoing findings, Dr. Tahsildar is debarred for 2 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 February 8, 2023, (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 application who knowingly uses the services of Dr. Tahsildar, in any capacity during his 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 Dr. Tahsildar, 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 Dr. Tahsildar during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 2, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023–02634 Filed 2–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0318—Revision]

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program: Allocations Forms

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 10, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program: Allocations Forms, OMB No. 0915–0318—Revision.

Abstract: HRSA administers the Ryan White HIV/AIDS Program (RWHAP) authorized under Title XXVI of the Public Health Service Act. The RWHAP Allocations and Expenditures Reports (A&E Reports) allow HRSA to monitor and track the use of grant funds for compliance with program and grants policies, and requirements as outlined in the legislation. To avoid duplication and reduce recipient reporting burden, HRSA created an electronic grantee contract management system (GCMS) that includes data required for various reports, including the Allocations Reports and other HRSA data reports, such as the RWHAP Services Report. Recipients can access GCMS year-round to upload or manually enter data on their service provider contractors or subrecipients, the RWHAP core medical and support services provided, and their funding amounts. Data required for Allocations Reports and other reports are automatically prepopulated from GCMS. Expenditures Report data are not auto-populated in the GCMS, and are still manually entered into the data reporting system.

Allocations and Expenditures (A&E) Reports

Recipients funded under RWHAP Parts A, B, C, and D are required to report financial data to HRSA at the beginning (Allocations Report) and at the end (Expenditures Report) of their grant budget period. The A&E Reports request information recipients already collect, including the use of RWHAP grant funds for core medical and support services; and on various program components, such as administration, planning and evaluation, and clinical quality management (CQM). RWHAP Parts A and B recipients funded under the