application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the 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, ROZLYTREK TABLETS (entrectinib). ROZLYTREK TABLETS (entrectinib) is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROSI*—positive and adult and pediatric patients 12 years of age and older with solid tumors that:

- have a neurotrophic tyrosine receptor kinase gene fusion without a known acquired resistance mutation;
- are metastatic or where surgical resection is likely to result in severe morbidity; and
- have progressed following treatment or have no satisfactory alternative therapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Subsequent to this approval, the USPTO received patent term restoration applications for ROZLYTREK TABLETS NDA 212725 (U.S. Patent Nos. 8,299,057; 8,673,893; 9,029,356; and 9,085,565) from Genentech, Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ROZLYTREK TABLETS 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 ROZLYTREK TABLETS is 1,968 days. Of this time, 1,727 days occurred during the testing phase of the regulatory review period, while 241 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:* March 28, 2014. The applicant claims March 29, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 28, 2014, 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:* December 18, 2018. FDA has verified the applicant's claims that the new drug application (NDA) for ROZLYTREK TABLETS (NDA 212725) was initially submitted on December 18, 2018.

3. *The date the application was approved:* August 15, 2019. FDA has verified the applicant's claims that NDA 212725 was approved on August 15, 2019.

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 864 days, 899 days, or 1,104 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: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16504 Filed 8–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0101]

Duniel Tejeda: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Duniel Tejeda 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 Duniel Tejeda was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Duniel Tejeda was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of April 20, 2022 (30 days after receipt of the notice), Mr. Tejeda had not responded. Mr. Tejeda's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable August 2, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from

providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On January 20, 2022, Mr. Duniel Tejeda was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Southern District of Florida-Miami Division, when the court accepted his plea of guilty and entered judgment against him for one count of conspiracy to commit mail and wire fraud in violation of 18 U.S.C. 1349.

As contained in the indictment, entered into the docket on February 24, 2021, and the Factual Proffer in support of Mr. Tejeda's guilty plea, entered into the docket on October 26, 2021, both from his case, Mr. Tejeda was a project manager and study coordinator employed at Tellus Clinical Research, Inc. (''Tellus''). Tellus was a medical research clinic located in Miami, Florida that conducted clinical trials on behalf of pharmaceutical companies and other sponsors. Among the clinical research trials conducted by Tellus were two studies of an investigational drug intended to treat opioid dependency, sponsored by Sponsor 1 and managed by clinical research organization (CRO) 1 (collectively, ''the opioid dependency trials''); two studies of an investigational drug intended to treat irritable bowel syndrome in female subjects, sponsored by Sponsor 2 and managed by CRO 2 (collectively, ''the IBS trials''); and one study of an investigational injectable drug intended to treat diabetic nephropathy, sponsored by Sponsor 3 and managed by CRO 3 (''the diabetes trial''). In Mr. Tejeda's roles with Tellus, he conspired with others to defraud these sponsors and CROs responsible for initiating and overseeing these clinical trials. For the purpose of obtaining money by means of materially false and fraudulent pretenses, representations, and promises, Mr. Tejeda, along with his co-conspirators, caused false information to be entered in subject case histories to make it appear that subjects had, among other things, satisfied the eligibility criteria to participate in the studies, provided informed consent to participate in the studies, received proper physical examinations, received or had been administered the investigational drug that was the subject of each clinical trial, and received payments for visits to Tellus for the clinical trials, when in fact Mr. Tejeda knew that such events had not occurred. As an example of Mr. Tejeda's specific conduct to further this scheme, in one of the opioid dependency trials, Mr. Tejeda entered his initials in the case history documentation for one of the study subjects to represent falsely that he had administered multiple doses of the investigational drug to the subject as required by the study protocol, and that this drug administration was witnessed by one of Mr. Tejeda's co-conspirators. As Mr. Tejeda well knew, these representations were false because the study subject was not participating in the study, Mr. Tejeda did not dose them with the study medication, and the dosing was not witnessed by Mr. Tejeda's co-conspirator.

In another instance, in connection to one of the IBS trials, Mr. Tejeda wrote a check, endorsed by one of his co-conspirators, to a study participant for their purported participation in a study visit. As Mr. Tejeda well knew, the individual was not in fact participating in the study and had not received the check. Mr. Tejeda deposited that check in his own bank account. Further, as part of the IBS trials, study subjects were required to make daily phone calls to an ''e-diary'' system (a toll-free number maintained by a third party) and report their personal experience with the study drug. Using the subjects' individual personal identification numbers, Mr. Tejeda, along with one or more of his co-conspirators, placed telephone calls to this e-diary system for the purposes of reporting fabricated data on behalf of purportedly legitimate study subjects.

As a result of this conviction, FDA sent Mr. Tejeda by certified mail on March 1, 2022, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Mr. Tejeda was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Mr. Tejeda an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning his debarment. Mr. Tejeda received the proposal on March 21, 2022. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Tejeda has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Tejeda is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act. Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Tejeda 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 during his period of debarment Mr. Tejeda 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 application from Mr. Tejeda during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Tejeda for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2022–N–0101 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16507 Filed 8–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0490]

Policy Regarding N-acetyl-L-cysteine; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Policy Regarding N-acetyl-L-cysteine.'' The guidance explains our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain N-acetyl-L-cysteine (NAC) and are labeled as dietary supplements. This enforcement discretion policy applies to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of ''dietary supplement'' and that are not otherwise in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on August 2, 2022.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0490 for ''Policy Regarding N-acetyl-L-cysteine: Guidance for Industry.'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 our consideration of comments. 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 comments 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lisa Bieniek, Center for Food Safety and Applied Nutrition, Office of Dietary Supplements and Programs (HFS–810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–4528; or Lauren Baham, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Policy Regarding N-acetyl-L-cysteine: Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. 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.

In the **Federal Register** of April 22, 2022 (87 FR 24170), we made available a draft guidance for industry entitled ''Policy Regarding N-acetyl-L-cysteine: Draft Guidance for Industry,'' which explained our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labeled as dietary supplements. In the draft guidance, we explained FDA determined that, under section