TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Latanoprost
Omidenepag isopropyl
Risperidone
Semaglutide
Tapinarof

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Albuterol sulfate
Betamethasone acetate; Betamethasone sodium phosphate
Budesonide; Formoterol fumarate dihydrate
Emtricitabine; Tenofovir alafenamide fumarate
Ferumoxytol
Fluticasone propionate
Fluticasone propionate; Salmeterol xinafoate
Fulvestrant
Gabapentin
Glatiramer acetate
Levalbuterol tartrate
Mometasone furoate
Naltrexone
Primidone
Semaglutide
Sotorasib
Soybean oil
Tiotropium bromide

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25485 Filed 11–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2333; FDA–2020–E–2334; FDA–2020–E–2336; and FDA–2020–E–2337]

Determination of Regulatory Review Period for Purposes of Patent Extension; ROZLYTREK INJECTION; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 8, 2022. The document announced the determination of the regulatory review period for ROZLYTREK INJECTION (entrectinib) for purposes of patent extension. The document was published with an incorrect dosage form. This notice corrects the dosage form of the drug product.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of July 8, 2022 (87 FR 40849), the dosage form for the human drug product ROZLYTREK (entrectinib), NDA 212726, is corrected from ''INJECTION'' to ''CAPSULES'' for all instances mentioned in the notice. Specifically, the drug product dosage form is corrected from ''INJECTION'' to ''CAPSULES'' in the following locations:

1. On page 40849, the following corrections are made:

- In the second column, the title of the document is corrected to read: ''Determination of Regulatory Review Period for Purposes of Patent Extension; ROZLYTREK CAPSULES.''
- In the second column, the first sentence under the **SUMMARY** section is corrected to read: ''The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ROZLYTREK CAPSULES and is publishing this notice of that determination as required by law.''
- In the third column, the first sentence under the section *Instructions* is corrected to read: ''All submissions received must include the Docket Nos. FDA–2020–E–2333; FDA–2020–E–2334; FDA–2020–E–2336; and FDA–2020–E–2337 for 'Determination of Regulatory Review Period for Purposes of Patent Extension; ROZLYTREK CAPSULES.'''

2. On page 40850, the following corrections are made:

- In the second column, under section I. Background of the **SUPPLEMENTARY INFORMATION** section, the third paragraph introduction is corrected to read: ''FDA has approved for marketing the human drug product, ROZLYTREK CAPSULES (entrectinib), NDA 212726, indicated for the treatment of:''
- In the second and third columns, under section I. Background of the **SUPPLEMENTARY INFORMATION** section, the last paragraph is corrected to read: ''Subsequent to this approval, the USPTO received patent term restoration applications for ROZLYTREK CAPSULES (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 CAPSULES represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.''
- In the third column, under II. Determination of Regulatory Review Period, the first sentence of the introductory paragraph is corrected to read: ''FDA has determined that the applicable regulatory review period for ROZLYTREK CAPSULES is 1,968 days.''
- In the third column, under II. Determination of Regulatory Review Period, the second sentence of the third paragraph is corrected to read: ''FDA

has verified the applicant's claims that the new drug application (NDA) for ROZLYTREK CAPSULES (NDA 212726) was initially submitted on December 18, 2018.''

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25489 Filed 11–16–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906–0034—Extension

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 16, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 945–0232.

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

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906–0034—Extension.

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency within HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). In 2018, the SRTR contractor implemented a pilot living donor registry in which transplant programs registered all potential living organ donors who provided informed consent to participate in the pilot registry. The Organ Procurement and Transplantation Network final rule, 42 CFR part 121, requires organ procurement organizations and transplant hospitals, ''as specified from time to time by the Secretary,'' to submit to the SRTR, as appropriate, information regarding ''donors of organs'' and ''other information that the Secretary deems appropriate.'' 42 CFR 121.11(b)(2).

In 2018, a pilot living donor registry was implemented by the SRTR, and each participating transplant program registered all potential candidates for living donation who provided informed consent to enroll. In 2019, an updated version of the data collection instrument was approved, followed by the latest data collection forms which were approved on February 26, 2021. These data collection modifications were intended to improve the quality of the data and reduce the administrative burden for respondents. This **Federal Register** notice requests an extension of the last approved data collection forms (February 2021) with no changes to the total estimated annualized burden hours.

Need and Proposed Use of the Information: The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the SRTR contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information to transplant programs for their future donor selection process and to aid potential living organ donors in their decision to pursue living donation.

Likely Respondents: Potential and actual living donors, transplant programs, medical and scientific organizations, and public organizations, including patient advocacy groups.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Average number of responses per respondent	Total number of responses	Average burden per response (in minutes)	Total burden hours
Potential Living Donor Registration form	[a] 16	112	1,792	0.27	484
Potential Living Donor Follow-up form	[b] 754	1	754	0.50	377
Reasons Did not Donate form (liver or kidney)	[a] 16	106	1,696	0.23	390