Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Pras Pathmanathan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm 1133, Silver Spring, MD 20993–0002, at 301–796–3490.

SUPPLEMENTARY INFORMATION:

I. Background

CM&S can be used in a variety of ways in medical device applications, including to perform ''in silico'' (virtual) device testing or to influence algorithms within software embedded in a device. This guidance provides a general risk-informed framework that can be used in the credibility assessment of CM&S used in medical device regulatory submissions. For the purposes of this guidance, CM&S refers to first principles-based (*e.g.,* physics-based or mechanistic) computational models, and not statistical or data-driven (*e.g.,* machine learning or artificial intelligence-based) models. This guidance is intended to help improve the consistency and transparency of the review of CM&S, to increase confidence in the use of CM&S in regulatory submissions, and to facilitate improved interpretation of CM&S credibility evidence submitted in regulatory submissions

A notice of availability of the draft guidance appeared in the **Federal Register** of December 23, 2021 (86 FR 72969). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revising the categorization of credibility evidence defined in the guidance, clarifying the scope of the guidance, and clarifying how the recommendations in the guidance relate to the framework described in the FDA-recognized standard American Society of Mechanical Engineers V&V 40, ''Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01500056 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-Submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25470 Filed 11–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by January 16, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances 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 its 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on August 22, 2023 (88 FR 57116). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

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

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

Active ingredient(s)
Azacitidine
Chlorhexidine gluconate
Cimetidine
Citalopram hydrobromide
Deucravacitinib
Deutetrabenazine
Dextroamphetamine
Edaravone
Ferric pyrophosphate citrate (multiple reference listed drugs)
Fingolimod lauryl sulfate
Furosemide
Futibatinib
Ganaxolone
Glycopyrrolate; Neostigmine methylsulfate
Halobetasol propionate; Tazarotene

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