TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

DSCSA small dispensers assessment	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with third-party entities related to enrollment	75	2	150	0.5	75
Coordination with third-party entities related to assessment questions response	50	2	100	2	200
Total	125				275

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Third-party disclosure activities. For those assessment participants that involve third-party activities, FDA is taking into consideration the time that participants will spend coordinating with third-party entities (*e.g.,* solution providers, wholesale distributors, consultants). For the enrollment, FDA estimates that 75 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. FDA estimates that each respondent will spend 2 hours coordinating with each third-party entity. Thus, for 150 respondents with an average of 2 partnering entities, the estimated total burden for coordinating with partnering entities related to the enrollment is 75 hours. FDA estimates that for each of the 100 lists of assessment responses, it will take approximately 2 hours to coordinate with each partner, resulting in a total of 200 hours. The total estimation for third-party disclosure burden is 275 hours (table 3).

Dated: March 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05294 Filed 3–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5616]

Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products.'' This draft guidance provides recommendations to applicants of approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nonprescription drug products on documenting minor labeling changes in the next annual report and provides examples of minor labeling changes that may be submitted in an annual report. The recommendations in this draft guidance address the types of minor labeling changes that may be appropriate to submit in an annual report to ensure that consumers have timely access to the most current labeling for a nonprescription drug product to ensure the product's safe and effective use. We anticipate that these recommendations may assist industry in understanding the circumstances in which it would be appropriate to document minor changes in the applicant's next annual report rather than submitting a prior approval supplement or ''changes being effected'' supplement, thereby reducing burden on industry and FDA.

DATES: Submit either electronic or written comments on the draft guidance by May 13, 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–2023–D–5616 for ''Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products.'' 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: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4139, Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products.'' This draft guidance provides recommendations to applicants of approved NDAs and ANDAs for nonprescription drug products on documenting minor labeling changes in the next annual report. The draft guidance also provides examples of minor labeling changes that may be submitted in an annual report.

FDA evaluates whether the data and information submitted as part of an NDA or ANDA for a nonprescription drug product demonstrate that the drug product is safe and effective for nonprescription use under the conditions prescribed, recommended, or suggested in its proposed labeling.[1] A nonprescription drug must be labeled with adequate directions for use.[2] Adequate directions for use are the directions under which the consumer can use the drug safely and for the purposes for which it is intended.[3] Therefore, labeling for a nonprescription drug product enables consumers to appropriately self-select and use the nonprescription drug product safely and effectively without the supervision of a healthcare practitioner.

After FDA approves an NDA or ANDA, an applicant may make, or in certain cases propose to FDA, changes to the approved application. Section 506A of the FD&C Act (21 U.S.C. 356a) and FDA regulations under §§ 314.70, 314.71, and 314.97 (21 CFR 314.70, 314.71, and 314.97) provide certain requirements for making and reporting to FDA changes to an approved NDA or ANDA, including an NDA or ANDA for a nonprescription drug product. Changes to an approved NDA or ANDA, including labeling changes, are categorized into one of three reporting categories: major, moderate, or minor.[4]

''Minor changes'' include certain changes that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.[5] Minor changes with an approved NDA or ANDA may be implemented immediately by the applicant without the applicant submitting a supplement to FDA. The applicant must document minor changes, including minor labeling changes, in its next annual report in accordance with § 314.81(b)(2) (21 CFR 314.81(b)(2)) (*i.e.,* the annual report covering the period when the change or changes occurred) submitted to FDA.[6] The annual report must include a summary of any changes in labeling, including minor changes, that have been made since the last report listed by date in the order in which they were implemented, or if no changes have been made, a statement of that fact.[7]

Determining the reporting category for a change to nonprescription drug labeling may present certain considerations that differ from changes to prescription drug labeling. Changes to the approved labeling for a nonprescription drug product may affect consumers' ability to appropriately self-select and use the nonprescription drug product safely and effectively without the supervision of a healthcare practitioner. Thus, changes to nonprescription labeling may not be considered minor even though similar changes may be considered minor when applied to the labeling of a prescription drug product. For example, certain changes in the layout of the package or container label for a prescription drug product that are consistent with FDA regulations (*e.g.,* 21 CFR part 201), without a change in the content of the labeling, might not affect the safe and effective use of the prescription drug product because it is used under the supervision of a healthcare practitioner. In contrast, changes in the layout of the package or container label and other changes to nonprescription drug labeling could affect consumers' ability to comprehend the nonprescription drug labeling and to appropriately self-select and use the nonprescription drug product such that the change would not be a minor change under § 314.70(d).

FDA generally does not expect that editorial and similar minor labeling changes to nonprescription drug labeling would affect consumers' ability to appropriately self-select and use the nonprescription drug product without the supervision of a healthcare practitioner. Based on FDA's experience approving nonprescription drug labeling, FDA is providing specific examples of such editorial or similar minor labeling changes for nonprescription drug products that may be appropriate to include in an annual report.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA

[1] See sections 505(d) and 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(d) and 353(b)(1)).

[2] See section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).

[3] See 21 CFR 201.5.

[4] See §§ 314.70 and 314.97; see also the guidance for industry entitled ''Changes to an Approved NDA or ANDA,'' available at *https://www.fda.gov/media/71846/download.*

[5] See § 314.70(d).

[6] See §§ 314.70(d) and 314.81(b)(2). Additionally, a representative sample of, among other things, the package labels must be submitted in the annual report (§ 314.81(b)(2)(iii)(*a*)).

[7] See § 314.81(b)(2)(iii)(*c*).

on ''Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products.'' 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. 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 21 CFR part 314 relating to the submissions of NDAs and ANDAs, supplemental applications, and annual reports have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 201 for the format and content requirements for nonprescription drug product labeling have been approved under OMB control number 0910–0340. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139.

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/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: March 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05293 Filed 3–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–2874]

Determination That Romidepsin Injection, 10 Milligrams/2 Milliliters (5 Milligrams/Milliliter) and 27.5 Milligrams/5.5 Milliliters (5 Milligrams/Milliliter), Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Romidepsin Injection, 10 milligrams (mg)/2 milliliters (mL) (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for romidepsin solution, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), that refer to these drugs as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Veniqua Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3267, *Veniqua.Stewart@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), are the subject of NDA 208574, held by Teva Pharmaceuticals USA, Inc. (Teva), and initially approved on March 13, 2020. Romidepsin Injection is currently indicated only for the treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy.

Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

E. Rust Consulting, LLC submitted a citizen petition dated July 11, 2023 (Docket No. FDA–2023–P–2874), under 21 CFR 10.30, requesting that the Agency determine whether Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

We note that Romidepsin Injection, 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL), previously were approved with an indication for treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of Teva's Romidepsin Injection for PTCL included a required postmarketing clinical trial intended to verify the clinical benefit of romidepsin (the Ro-CHOP study) for PTCL. Teva's Romidepsin Injection product was approved under the 505(b)(2) approval pathway, and the listed drug relied upon is Celgene Corp.'s (Celgene) NDA 022393, ISTODAX (romidepsin) for injection, 10 mg/vial. Celgene was acquired by Bristol-Meyers Squib Co. which is