is a basis to conclude that an attribute of each approved drug product makes each one medically unsuitable to treat certain patients for their condition, an interpretation that protects patients and the integrity of the drug approval process. The nominations proposing to compound drug products in ready-to-use form containing bulk drug substances in one or more FDA-approved drug products do not show that the approved drug product, when not manufactured in the ready-to-use form, is medically unsuitable for certain patients. Nor do the nominations and comments establish that drug products in the relevant concentrations, including ready-to-use products, cannot be prepared from the approved drug products. Rather, they propose to compound a ready-to-use product from bulk drug substances to seek improved efficiency for prescribers or healthcare providers, or to address the possibility that the approved drug might be mishandled by a medical professional, neither of which falls within the meaning of clinical need to compound a drug product using a bulk drug substance.

Two comments requested changes to the Interim Policy. These comments are outside the scope of FDA's bulk drug substance evaluations and decisions that are the subject of this notice. FDA welcomes public comments on its guidance documents that address human drug compounding. We encourage comments on the Interim Policy to be submitted the docket for the guidance, docket number FDA–2015–D–3539. Comments may be submitted to this docket at any time on *https://www.regulations.gov.*

V. Conclusion

For the reasons stated above, we find that there is a clinical need for outsourcing facilities to compound using the bulk drug substances DPCP for topical use only, glycolic acid for topical use only in concentrations up to 70 percent, SADBE for topical use only, and TCA for topical use only and, therefore, we are now including them on the 503B Bulks List. In addition, we find that there is no clinical need for outsourcing facilities to compound using the bulk drug substances diazepam, dipyridamole, dobutamine HCl, dopamine HCl, edetate calcium disodium, folic acid, glycopyrrolate, and sodium thiosulfate (except for topical administration), and therefore we are not including these bulk drug substances on the 503B Bulks List.

VII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. FDA, Guidance for Industry, ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' January 2017 (available at *https://www.fda.gov/media/94402/download*).

*2. FDA, Guidance for Industry, ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' March 2019 (available at *https://www.fda.gov/media/121315/download*).

*3. FDA Memorandum to File, Clinical Need for Diphenylcyclopropenone (DPCP) in Compounding Under Section 503B of the FD&C Act, July 2020.

*4. FDA Memorandum to File, Clinical Need for Glycolic Acid in Compounding Under Section 503B of the FD&C Act, July 2020.

*5. FDA Memorandum to File, Clinical Need for Squaric Acid Dibutyl Ester (SADBE) in Compounding Under Section 503B of the FD&C Act, July 2020.

*6. FDA Memorandum to File, ''Clinical Need for Trichloroacetic Acid (TCA) in Compounding Under Section 503B of the FD&C Act,'' July 2020.

7. Leheta, T. M., A. El Tawdy, R. M. Abdel Hay, and S. Farid, 2011, ''Percutaneous Collagen Induction Versus Full-Concentration Trichloroacetic Acid in the Treatment of Atrophic Acne Scars,'' *Dermatologic Surgery,* 37(2):207–216.

8. Kumari, R. and D. M. Thappa, 2010, ''Comparative Study of Trichloroacetic Acid Versus Glycolic Acid Chemical Peels in the Treatment of Melasma,'' *Indian Journal of Dermatology, Venereology and Leprology,* 76:447, available at *https://ijdvl.com/comparative-study-of-trichloroacetic-acid-versus-glycolic-acid-chemical-peels-in-the-treatment-of-melasma/.*

9. Nigwekar, S. U., S. M. Brunelli, D. Meade, et al., 2013, ''Sodium Thiosulfate Therapy for Calcific Uremic Arteriolopathy,'' *Clinical Journal of the American Society of Nephrology,* 8(7):1162–1170.

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11. Udomkarnjananun, S., K. Kongnatthasate, K. Praditpornsilpa, et al., 2019, ''Treatment of Calciphylaxis in CKD: A Systematic Review and Meta-Analysis,'' *Kidney International Reports,* 4(2):231–244.

12. Schulz, L. T., E. J. Elder, Jr, K. J. Jones, et al., 2010, ''Stability of Sodium Nitroprusside and Sodium Thiosulfate 1:10 Intravenous Admixture,'' *Hospital Pharmacy,* 45(10):779–784.

*13. FDA Guidance for Industry, Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act, December 2016 (available at *https://www.fda.gov/media/97347/download*).

14. Pun, Patrick H. and John P. Middleton, 2017, ''Dialysate Potassium, Dialysate Magnesium, and Hemodialysis Risk,'' *Journal of the American Society of Nephrology,* 28: 3441–3451.

15. De Nicola, L., V. Bellizzi, R. Minutolo, et al., 2000, ''Effect of Dialysate Sodium Concentration on Interdialytic Increase of Potassium,'' *Journal of the American Society of Nephrology,* 11:2337–2343.

Dated: January 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01558 Filed 1–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0092]

Revising Abbreviated New Drug Application Labeling Following Revision of the Reference Listed Drug Labeling; Draft Guidance 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 a draft guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' This guidance provides recommendations for updating labeling for abbreviated new drug applications (ANDAs) following revisions to the labeling of a reference listed drug (RLD), including information on how to identify RLD labeling updates and how to submit labeling updates to both unapproved and approved ANDAs to conform to RLD labeling updates. This draft guidance revises the guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling'' issued in April 2000.

DATES: Submit either electronic or written comments on the draft guidance by March 28, 2022 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–2022–D–0092 for ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' 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: Jonathan Hughes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1688, Silver Spring, MD 20993–0002, 301–796–9291.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' This guidance provides recommendations for updating labeling for ANDAs following revisions to the labeling of an RLD, including information on how to identify RLD labeling updates and how to submit labeling updates to both unapproved and approved ANDAs to conform to RLD labeling updates. This draft guidance revises the guidance for industry ''Revising ANDA Labeling Following Revision of the RLD Labeling'' issued in April 2000. Significant changes from the 2000 version include updates to outdated details about how to obtain information on changes to RLD labeling and how to submit revised ANDA labeling to FDA.

A generic drug is required to have the same labeling as the RLD, except for changes required because of differences approved under a suitability petition (see section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) (21 U.S.C. 355(j)(2)(C) and 21 CFR 314.93) or because the generic drug and the RLD are produced or distributed by different manufacturers (see *e.g.,* section 505(j)(2)(A)(v) of the FD&C Act and § 314.94(a)(8)(iv) (21 CFR 314.94(a)(8)(iv))). FDA regulations provide examples of permissible differences in labeling that may result when a proposed generic drug and the RLD are ''produced or distributed by different manufacturers,'' including the omission of an indication or other aspect of labeling protected by patent or exclusivity and ''labeling revisions made to comply with current FDA labeling guidelines or other guidance'' (§ 314.94(a)(8)(iv)).

An ANDA holder is expected to update its labeling after FDA has approved relevant changes to the labeling for the corresponding RLD. Prompt revision, submission to the Agency, and implementation of revised labeling are important to ensure that the generic drug continues to be as safe and effective as the corresponding RLD. Because the labeling of a generic drug must be the same as the labeling for the RLD, except for permissible differences, the revision should be made at the earliest time possible.

In this draft guidance, FDA is providing information on how ANDA applicants and holders should monitor for changes to RLD labeling, procedures for the electronic submission of labeling

updates, information describing the type of submission that should be made to FDA, as well as other considerations for submitting a labeling update to FDA.

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 on ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA.

- The collections of information in part 314 for the submission of ANDAs (including the content and format of ANDAs and supplements and amendments) have been approved under OMB control number 0910–0001 and in part 314 (included under the 21 CFR parts 10 through 16 hearing regulations) for OMB control number 0910–0191.
- The collections of information pertaining to the electronic submission of labeling changes have been approved under OMB control number 0910–0045.
- The collections of information pertaining to the content and format requirements for human prescription drugs and biological products and the submission of such labeling have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *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: January 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01577 Filed 1–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4337]

Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the following virtual public meeting entitled ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' The purpose of the virtual public meeting and the request for comments is to fulfill FDA's commitment to seek stakeholder input related to data standards and the electronic submission system's past performance, future targets, emerging industry needs, and technology initiatives. FDA will use the information from the public meeting as well as from comments submitted to the docket to provide input into data standards and electronic submissions initiatives.

DATES: The public meeting will be held on April 12, 2022, from 9 a.m. to 1 p.m. Eastern Time, and will take place virtually, held by webcast only. Submit either electronic or written comments on this public meeting by March 22, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 22, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 22, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2018–N–4337 for ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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