B. Cell and Gene Therapy Products, Where One Lot Treats a Single Patient

In accordance with section 510(j)(3)(B) of the FD&C Act, this order exempts cell and gene therapy products, where one lot treats a single patient, from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution, is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Manufacturers of cell and gene therapy products, where one lot treats a single patient, maintain a highly controlled and secure supply chain from initial request for treatment of a patient to final product delivery to the site where the treatment occurs. This is because, due to the nature of these products, manufacturers implement strict chain of identity procedures to track products through the manufacturing process, to make sure the correct product gets to the correct patient. Additionally, the supply chains for these products are well-established and well-understood from information described in the BLA, and generally do not involve wholesale distributors, brokers, or other intermediaries.

Additionally, pursuant to § 600.81 (21 CFR 600.81), the Agency generally receives lot distribution reports every 6 months from BLA holders. Specifically, reports submitted to the Agency under § 600.81 include, among other information, the fill lot numbers for the total number of dosage units of each strength or potency distributed, the label lot number (if different from fill lot number), the number of doses in fill lot/label lot, and the date of release of fill lot/label lot for distribution. For this category of biological products, because one lot treats a single patient, the lot distribution reports submitted to the Agency under § 600.81 represent the amount of product manufactured for commercial distribution, and additional reporting of such information under section 510(j)(3)(A) of the FD&C Act would be redundant.

IV. Paperwork Reduction Act of 1995

This final order contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The information collection provisions of this final order are approved under 0910–0045.

V. Effective Date

This final order is effective 30 days after its date of publication in the **Federal Register**.

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07772 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1254]

Assessing Adhesion With Transdermal and Topical Delivery Systems for Abbreviated New Drug Applications; Revised 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 revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs'' (Revision 2). This draft guidance (Revision 2) revises the Revision 1 draft guidance of the same name, which was announced in the **Federal Register** on October 10, 2018. This revised draft guidance provides recommendations for the design and conduct of studies evaluating the adhesion performance of a transdermal or topical delivery system (collectively referred to as TDS). Depending on the objectives of a generic TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only, or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and bioequivalence (BE) with pharmacokinetic (PK) endpoints). The recommendations in this revised draft guidance relate to studies submitted in support of an abbreviated new drug application (ANDA).

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 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 2016–D–1254 for ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Mannion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs'' (Revision 2). This revised draft guidance (Revision 2) revises the Revision 1 draft guidance of the same name, which was announced in the **Federal Register** on October 10, 2018 (83 FR 50942). FDA received five comments on the revised draft guidance (Revision 1), which were considered before publication of this revised draft guidance (Revision 2).

This revised draft guidance (Revision 2) provides recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS submitted in support of an ANDA. Depending on the objectives of a TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and BE with PK endpoints). FDA recommends that applicants consult this revised draft guidance (Revision 2) in conjunction with any relevant product-specific guidances for industry when considering the design and conduct of studies that may be appropriate to support the BE of a proposed generic TDS product to its reference listed drug and/or reference standard product.

Specifically, in response to the comments received from industry, FDA is clarifying the following components of the guidance. When recording measurements of TDS adhesion, applicants may use appropriate methods (*e.g.,* a trained visual assessment and/or dot matrix templates) and are encouraged to explore the use of alternative scales (other than the five-point adhesion scale) to estimate the percentage of the entire TDS surface area that is adhered to the skin. At each adhesion assessment time point, applicants should also record photographic evidence showing the extent of TDS adhesion to the skin. Because percent adhesion can span a range and yet be classified as a single score, the photographic evidence can be used to support the visual observation of the percent adhesion reported at each time point and is not intended to be used for automated or photometric analysis at this time. Additional clarity is also provided related to the statistical analysis of data. Finally, FDA recommends that an applicant who seeks to use an alternative approach to FDA's recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS to contact the Agency to discuss the proposed alternative approach to evaluate adhesion performance for that particular drug product.

This revised draft guidance (Revision 2) is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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 revised draft guidance (Revision 2) 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 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

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

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07770 Filed 4–12–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3546]

Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.