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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: David Coppersmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Silver Spring, MD 20993, 301–796–9193.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Data Integrity for In Vivo Bioavailability and Bioequivalence Studies.''

Requirements for submitting BA and BE data in INDs, NDAs, ANDAs, and amendments and supplements to these applications, the definitions of BA and BE, and the types of in vitro and in vivo studies that are appropriate to measure BA and establish BE are set forth in parts 312, 314, and 320 (21 CFR parts 312, 314, and 320). Requirements for BLAs and amendments and supplements to these applications are included in part 601 (21 CFR part 601). FDA expects that all data submitted to the Agency, including data from BA and BE studies submitted in support of INDs, NDAs, and ANDAs and clinical pharmacologic studies submitted in support of BLAs, are accurate, complete, and reliable, and that industry maintain data integrity throughout the data lifecycle of the product(s) or biologic therapeutic(s). In recent years, however, FDA has observed data integrity concerns during the inspection of testing sites, clinical testing sites, and analytical testing sites, and during the assessment of the BA and BE study data submitted in support of applications. Data integrity concerns can impact application acceptance for filing, assessment, regulatory actions, and approval as well as post-approval actions, such as therapeutic equivalence ratings.

This guidance provides recommendations to achieve and maintain data integrity with respect to (1) applicants, (2) testing site management, and (3) implementation and management of a quality management system. This guidance does not include a comprehensive list of all best practices that applicants and testing sites should use to achieve and maintain data integrity. It is each applicant's responsibility to achieve and maintain data integrity for their studies, which includes identifying and implementing the most effective and efficient risk-based controls. FDA encourages applicants and testing site management to review FDA regulations and all applicable guidance for industry to understand FDA's current thinking on a topic.

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 ''Data Integrity for In Vivo Bioavailability and Bioequivalence Studies.'' 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 part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in part 314 for new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in part 601 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information found in 21 CFR part 11 pertaining to electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information found in 21 CFR parts 50 and 56 pertaining to protection of human subjects, institutional review boards and informed consent have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 58 for good laboratory practices for have been approved under OMB control number 0910–0119. The collections of information found in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice (CGMP) and the recordkeeping requirement for CGMP sample retention 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 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07080 Filed 4–2–24; 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 Guidance for Oxymetazoline Hydrochloride; 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 ''Draft Guidance on Oxymetazoline Hydrochloride.'' The draft guidance,

when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for oxymetazoline hydrochloride ophthalmic solution.

DATES: Submit either electronic or written comments on the draft guidance by June 3, 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 ''Draft Guidance on Oxymetazoline Hydrochloride.'' 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. This notice announces the availability of a draft product-specific guidance on generic oxymetazoline hydrochloride ophthalmic solution.

FDA initially approved new drug application 212520 UPNEEQ (oxymetazoline hydrochloride) in July 2020. We are now issuing a draft guidance for industry on, among other things, BE recommendations for generic oxymetazoline hydrochloride ophthalmic solution (''Draft Guidance on Oxymetazoline Hydrochloride'').

In June 2021, RVL Pharmaceuticals, Inc. (RVL) submitted a citizen petition requesting, among other things, that FDA withhold approval of any ANDA or section 505(b)(2) application that references or relies upon UPNEEQ (oxymetazoline hydrochloride ophthalmic solution), unless certain conditions are satisfied, including conditions related to demonstrating BE (Docket No. FDA–2021–P–0533). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the draft guidance entitled ''Draft Guidance on Oxymetazoline Hydrochloride'' before responding to RVL's citizen petition. FDA's issuance of the draft guidance on oxymetazoline hydrochloride ophthalmic solution does not represent a final decision on the issues raised in the petition.

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 ''Draft Guidance on Oxymetazoline Hydrochloride.'' 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

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

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 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06985 Filed 4–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Assessing Strategies To Promote Children's Engagement and Active Participation in Virtual Visits

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing Strategies to Promote Children's Engagement and Active Participation in Virtual Home Visits OMB No. 0915–xxxx—[NEW]

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, title V, section 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies to provide home visiting services to eligible families in at-risk communities.

This information collection is part of the Assessing and Describing Practice Transitions Among Evidence-Based Home Visiting Programs in Response to the COVID–19 Public Health Emergency Study, which aims to identify and study practices implemented in response to the COVID–19 public health emergency that support evidence-based practice and have the potential to enhance home visiting programming. One of the practices the study identified is strategies home visitors use to engage children and promote their active engagement during virtual visits. The purpose of this information collection is to better understand, through rapid cycle learning, how MIECHV-funded home visiting programs can implement virtual strategies improve child engagement and how home visitors can apply these strategies during in-person service delivery.

Information will be collected in four phases designed to (1) identify virtual child engagement strategies (co-definition phase); (2) pilot test and identify refinements to improve the implementation of strategies (installation phase); (3) iteratively test the strategies with refinements to their implementation (refinement phase); and (4) assess the potential of these child engagement strategies to improve service delivery and promote family engagement and family satisfaction with home visiting programs in both virtual and in-person settings (summary phase). Data collection activities include focus groups, online questionnaires, and review of documents and administrative data.

A 60-day notice published in the **Federal Register** on December 5, 2023, 88 FR 84340–41. There were no public comments. One home visiting model developer requested copies of the information collection forms.

Need and Proposed Use of the Information: With the end of the COVID–19 public health emergency, most MIECHV-funded home visiting programs have transitioned back to some level of in-person service delivery. However, many continue to offer occasional virtual home visits if warranted and appropriate, such as during inclement weather or due to family and staff health concerns. Understanding the virtual strategies that home visitors used or are using to address the challenges of engaging children during virtual home visits, how these strategies can be implemented, how these strategies and learned lessons can be applied to in-person settings, and how children and families respond to these strategies will be valuable to the field. HRSA intends to use collected information to share evidence-informed resources and strategies that MIECHV awardees can use to optimize children's engagement and active participation and strengthen their home visiting services.

Likely Respondents: Respondents include (1) families who receive home visiting services and (2) MIECHV-funded home visiting program staff, which may include program directors, managers, supervisors, and home visitors.

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