ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
2024 NSECE Household Follow-up Questionnaire	3,750	1	.36	1,350
2024 NSECE Workforce Follow-up Questionnaire (Classroom Staff)	5,550	1	.33	1,832

Estimated Total Annual Burden Hours: 3,182.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Child Care and Development Block Grant Act of 1990, as amended by the CCDBG Act of 2014 (Pub. L. 113–186). Social Security Act, section 418 as extended by the Continuing Appropriations Act of 2017 and the TANF Extension Act of 2019. Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–06982 Filed 4–2–24; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1245]

Data Integrity for In Vivo Bioavailability and Bioequivalence Studies; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Data Integrity for In Vivo Bioavailability and Bioequivalence Studies.'' The purpose of this guidance is to provide recommendations to applicants and testing site management on achieving and maintaining data integrity for the clinical and bioanalytical portions of bioavailability (BA) and bioequivalence (BE) studies submitted in support of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and the bioanalytical portion of clinical pharmacologic studies supporting Center for Drug Evaluation and Research-regulated biologic license applications (BLAs) as well as amendments and supplements to these applications. In addition, the recommendations in this guidance apply to the bioanalytical portion of nonclinical studies. FDA also encourages applicants and testing sites to consider these recommendations when conducting other studies, including in vitro and pharmacology and toxicology studies.

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–2024–D–1245 for ''Data Integrity for Bioavailability and Bioequivalence Studies at Testing Sites.'' 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: 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,