TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Pretest					
Pretest Screener Completes	400	1	400	0.03 (2 minutes)	12
Pretest Questionnaire Completes	80	1	80	0.30 (18 minutes)	24
Main Study					
Main Study Screener Completes	3,200	1	3,200	0.03 (2 minutes)	96
Main Study Questionnaire Completes	640	1	640	0.30 (18 minutes)	192
Total					324

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

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 also are 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. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Wojdynski, B.W. and G.J. Golan, ''Native Advertising and the Future of Mass Communication,'' *American Behavioral Scientist,* vol. 60, pp. 1403–1407, 2016, *https://doi.org/10.1177/0002764216660134*.
2. King, J., ''Native Advertising: What It Is and How It Benefits Advertisers and Publishers,'' EMARKETER, October 11, 2023. Available at: *https://www.emarketer.com/insights/native-ad-spending. Accessed on June 12, 2024*.
3. Campbell, C. and L.J. Marks, ''Good Native Advertising Isn't a Secret,'' *Business Horizons,* vol. 58, pp. 599–606, 2015, *https://doi.org/10.1016/j.bushor.2015.06.003*.
4. Campbell, C. and P.E. Grimm, ''The Challenges Native Advertising Poses: Exploring Potential Federal Trade Commission Responses and Identifying Research Needs,'' *Journal of Public Policy & Marketing,* vol. 38, pp. 110–123, 2019, *https://doi.org/10.1177/0743915618818576*.
5. Campbell, M.C. and A. Kirmani, ''Consumers' Use of Persuasion Knowledge: The Effects of Accessibility and Cognitive Capacity on Perceptions of an Influence Agent,'' *Journal of Consumer Research,* vol. 27, pp. 69–83, 2000, *https://doi.org/10.1086/314309*.
6. Wei, M.-L., E. Fischer, and K.J. Main, ''An Examination of the Effects of Activating Persuasion Knowledge on Consumer Response to Brands Engaging in Covert Marketing,'' *Journal of Public Policy & Marketing,* vol. 27, pp. 34–44, 2008, *https://doi.org/10.1509/jppm.27.1.34*.
7. Pierre, L., ''The Effect of Covert Advertising Recognition on Consumer Attitudes: A Systematic Review,'' *Journal of Marketing Communications,* pp. 1–22, 2023, *https://doi.org/10.1080/13527266.2023.2184851*.
8. Hastak, M. and M.B. Mazis, ''Deception by Implication: A Typology of Truthful but Misleading Advertising and Labeling Claims,'' *Journal of Public Policy & Marketing,* vol. 30, pp. 157–167, 2011, *http://www.jstor.org/stable/23209271*.
9. Cain, R.M., ''Embedded Advertising on Television: Disclosure, Deception, and Free Speech Rights,'' *Journal of Public Policy & Marketing,* vol. 30, pp. 226–238, 2011, *https://doi.org/10.1509/jppm.30.2.226*.
10. Lee, S.S., H. Chen, and Y.-H. Lee, ''How Endorser-Product Congruity and Self-Expressiveness Affect Instagram Micro-Celebrities' Native Advertising Effectiveness,'' *Journal of Product & Brand Management,* vol. 31, pp. 149–162, 2022, *https://www.emerald.com/insight/content/doi/10.1108/JPBM-02-2020-2757/full/html*.

*11. Untitled Letter to Aclaris Therapeutics, Inc. (June 14, 2019). Available at: *https://www.fda.gov/media/128151/download?attachment*.

*12. Untitled Letter to Biohaven Pharmaceuticals (March 8, 2021). Available at: *https://www.fda.gov/media/146528/download?attachment*.

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22575 Filed 10–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1105]

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers; 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 final guidance for industry entitled ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' The guidance provides information for sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs. The guidance provides recommendations regarding the requirements in our regulations, pursuant to which FDA considers electronic systems, electronic records, and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. This guidance finalizes the draft guidance of the same title issued on March 16, 2023, and supersedes the guidance for industry entitled ''Computerized Systems Used in Clinical Investigations'' issued in May 2007.

DATES: The announcement of the guidance is published in the **Federal Register** on October 2, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2017–D–1105 for ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' 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 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Elizabeth Kunkoski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3332, Silver Spring, MD 20993–0002, 301–796–6439, *Elizabeth.Kunkoski@fda.hhs.gov;* James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G318, Silver Spring, MD 20993–0002, 301–796–6539, *Soma.Kalb@fda.hhs.gov;* Yuguang Wang, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 4A–012, College Park, MD 20740, 240–402–1757, *Yuguang.Wang@fda.hhs.gov;* Justin Sherren, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Silver Spring, MD 20993–0002, 240–402–7970, *CTP-BIMO@fda.hhs.gov;* Eric Nelson, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN #4, Rm. 106, Rockville, MD 20855, 240–402–5642, *Eric.Nelson@fda.hhs.gov;* or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567, *paul.kluetz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' The guidance provides information for sponsors, clinical investigators, IRBs, CROs, and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs. The goals of the guidance are to: (1) update recommendations for applying and implementing data integrity and data security controls, including the use of audit trails and the protection of records in the current environment of electronic systems used in clinical investigations; (2) expand upon recommendations on the risk-based approach to validation of electronic systems described in the guidance for industry ''Part 11, Electronic Records; Electronic

Signatures—Scope and Application'' (August 2003); (3) provide recommendations on using information technology service providers to provide services during a clinical investigation; (4) provide recommendations regarding the collection of data through digital health technologies; (5) facilitate the use of electronic signatures; and (6) facilitate the use of electronic systems, electronic records, and electronic signatures to improve the quality and efficiency of clinical investigations.

This guidance finalizes the draft guidance of the same title issued on March 16, 2023 (88 FR 16268). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) clarifying the applicability of part 11 (21 CFR part 11) to real-world data sources submitted to FDA; (2) clarifying the applicability of part 11 to clinical investigations conducted outside of the United States; (3) describing electronic systems deployed by regulated entities in clinical investigations and using a risk-based approach for validation; (4) clarifying the focus of FDA inspections of regulated entities; (5) providing recommendations for agreements between information technology service providers and regulated entities; (6) providing recommendations regarding data collection from digital health technologies used in clinical investigations; and (7) clarifying recommendations for the use of electronic signatures in clinical investigations, including information on submission of letters of non-repudiation to certify that an electronic signature is the legally binding equivalent of a traditional handwritten signature. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' 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 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR parts 314 and 601 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22562 Filed 10–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4310]

Center for Drug Evaluation and Research Quantitative Medicine Center of Excellence; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing this notice to announce the establishment of the Center for Drug Evaluation and Research (CDER) Quantitative Medicine Center of Excellence (QM CoE). Quantitative medicine (QM) is used to inform premarket product review, post-market product assessment, policy development, and policy implementation within several CDER offices. The QM CoE will act as a coordinating body that drives innovation and facilitates integration of QM methodologies and principles across CDER. To realize this purpose, the QM CoE will introduce new activities and coordinate existing activities in key areas, including multidisciplinary education and exchange, development and implementation of applied science policy, knowledge management, and community engagement.

DATES: The formation of the QM CoE was announced on March 25, 2024. For more details, please visit *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-quantitative-medicine-center-excellence-qm-coe.*

FOR FURTHER INFORMATION CONTACT: Daphne Guinn, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–837–7122, *Daphne.Guinn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

QM involves the development and application of exposure-based, biological, and quantitative modeling and simulation approaches derived from nonclinical, clinical, and real-world sources to inform: (1) drug development, (2) regulatory decision-making, and (3) patient care. The technical scope includes pharmaco-statistical modeling, mechanistic modeling, biomarker-endpoint development, artificial intelligence and machine learning, and clinical trial simulations and in silico predictions. Within CDER, QM approaches have been used to inform premarket product review, post-market product assessment, policy development, and policy implementation.

While CDER has been at the forefront of advancing QM over the decades, the efforts in outreach and education, scientific and regulatory initiatives, and operations have largely been decentralized. Recognizing the opportunity for synergy, CDER has begun a coordinated QM effort that maximally leverages its subject matter