on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

Description of Respondents: Respondents to this collection of information are applicants and nonapplicants as defined in 21 CFR 514.3. Respondents include individuals and the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated feed reports, 510.301(a) and (b).	N/A	8	1	8	.25 (15 minutes) ..	2
Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3), and (4)(iv)(A) and (C).	1932	85	1249	98,639	1	98,639
Voluntary reporting FDA Form 1932a for the public.	1932a	106	1	106	1	106
514.80(b)(4) Periodic Drug Experience Reports.	2301	79	20	1,582	16	25,312
514.80(b)(5)(i) Special Drug Experience Reports.	2301	78	215	16,790	2	33,580
514.80(b(5)(ii) Advertisement and Promotional labeling.	2301	38	192	7,282	2	14,564
514.80(b)(5)(iii) Distributor's Statements ...	2301	22	2	36	2	72
514.80(d)(2)	N/A	1	1	1	1	1
Total	.....	.....	.....	.....	.....	172,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping, 510.301 [2]	8	1	8	4	32
Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e) [3]	79	1,575.14	124,436	14	1,742,104
Total	.....	.....	.....	.....	1,742,136

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.
[3] This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and conditional NADAs under § 514.80(e).

Upon review of the information collection, we have adjusted our estimated burden to reflect an overall increase of 136,029.75 hours and 1,677,019 responses/records, annually.

Dated: December 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27817 Filed 12–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–3054]

M11 Clinical Electronic Structured Harmonised Protocol; International Council for Harmonisation; Draft Guidance for Industry; Draft Template; and Technical Specification; 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 ''M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP),'' and two supplemental documents entitled ''M11 Template,'' and ''M11 Technical Specification.'' The draft guidance, template, and technical specification were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The draft guidance provides recommendations for a harmonized clinical trial protocol including the organization of standardized content and formatting. The draft template identifies headers, common text, and a set of data fields and terminologies that will be the basis for efficiencies in data exchange. The technical specification recommends the use of an open, non-proprietary standard to enable electronic exchange of clinical protocol information. The intent of the draft guidance and supporting documents is to create an international standard for the content and exchange of clinical trial protocol information facilitating review and assessment by regulators, sponsors,

ethical oversight bodies, investigators, and other stakeholders.

DATES: Submit either electronic or written comments on the draft guidance by February 21, 2023 to ensure that the Agency considers your comment on this draft guidance, template, and technical specification before it begins work on the final versions.

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–3054 for ''M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP).'' 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Veronica Pei, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5338, Silver Spring, MD 20993–0002, 240–402–7091, *Yangveronica.Pei@fda.hhs.gov.*

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP),'' and two supplemental documents entitled ''M11 Template,'' and ''M11 Technical Specification.'' The draft guidance, template, and technical specification were prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and

industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In September 2022, the ICH Assembly endorsed the draft guideline entitled ''M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP)'' and two supplemental documents entitled ''M11 Template,'' and ''M11 Technical Specification'' and agreed that the materials should be made available for public comment. The draft guideline and supplemental documents are the product of the Multidisciplinary Expert Working Group of the ICH. Comments about these draft guidances will be considered by FDA and the Multidisciplinary Expert Working Group.

The draft guidance provides recommendations for a harmonized clinical trial protocol including the organization of standardized content and formatting. The draft template identifies headers, common text, and a set of data fields and terminologies that will be the basis for efficiencies in data exchange. The technical specification recommends the use of an open, nonproprietary standard to enable electronic exchange of clinical protocol information. The intent of the draft guidance and supporting documents is to create an international standard for the content and exchange of clinical trial protocol information facilitating review and assessment by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders.

The draft guidance has been left in the original ICH format. The final guidance and supporting materials will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, template, and technical specification when finalized, will represent the current thinking of FDA on the topics they address. They do not establish any rights for any person and are 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 21 CFR part 312 pertaining to clinical trial design and protocols have been approved under OMB control number 0910–0014. The collections of information pertaining to good clinical practice and for the implementation of improved and efficient approaches to clinical trial design have been approved under OMB control number 0910–0843.

III. Electronic Access

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

Dated: December 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27832 Filed 12–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel Fellowships in Digestive Diseases and Nutrition.

Date: February 16–17, 2023.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7011, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 16, 2022.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–27823 Filed 12–21–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice To Announce the Updated Significant Changes to the Revised NIH Grants Policy Statement for Fiscal Year 2023

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) announces publication of the updated Significant Changes that have already been made to the NIH Grants Policy Statement (NIHGPS) in fiscal year 2022 that will be reflected in the GPS for fiscal year 2023. The NIHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of award for all NIH grants and cooperative agreements, and extensive guidance to those who are interested in pursuing NIH grants. This update incorporates significant changes for FY 2023, such as new and modified