insurance cost sharing collection, and 307 additional hours due to the pilot test on sampling NHIS nonrespondents account for the difference. While the burden associated with these added tasks totals 7,602 hours, reductions in other burden estimates leave a net difference of 7,264 hours overall.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
MEPS–HC				
MEPS–HC Core Interview	* 13,338	51,129	* $24.34	$1,244,479
Adult Female SAQ (PSAQ)–Years 2019 and 2021; Adult SAQ (SAQ)—Year 2020	12,984	1,515	* 24.34	36,875
Adult Male SAQ (PSAQ)—Years 2019 and 2021; Adult SAQ (SAQ) -Year 2020	11,985	1,398	* 24.34	34,027
Diabetes care SAQ	2,072	104	* 24.34	2,531
Mental Health Questions Included in Adult SAQ (Male/Female)—Year 2020	20,476	1,194	* 24.34	29,062
Authorization forms for the MEPS–MPC Provider Survey	12,804	3,457	* 24.34	84,143
Authorization form for the MEPS–MPC Pharmacy Survey	12,804	1,985	* 24.34	48,314
Health Insurance Cost Sharing Collection—2020	6,258	6,101	* 24.34	148,498
MEPS–HC Validation Interview	4,225	352	* 24.34	8,567
Pilot Test on Sampling NHIS Nonrespondents—2020	200	307	* 24.34	7,472
Subtotal for the MEPS–HC	102,366	67,542	na	1,643,968
MEPS–MPC				
MPC Contact Guide/Screening Call	36,598	1,220	** 17.25	21,045
Home care for health care providers questionnaire	635	146	** 17.25	2,519
Home care for non-health care providers questionnaire	11	2	** 17.25	35
Office-based providers questionnaire	11,210	3,083	** 17.25	53,182
Separately billing doctors questionnaire	12,397	9,294	** 17.25	160,322
Hospitals questionnaire	5,310	2,597	** 17.25	44,798
Institutions (non-hospital) questionnaire	116	36	** 17.25	621
Pharmacies questionnaire	6,919	1,010	*** 15.90	16,059
Subtotal for the MEPS–MPC	73,196	17,388	na	298,580
Grand Total	175,562	na	na	1,942,548

* Mean hourly wage for All Occupations (00–0000).
** Mean hourly wage for Medical Secretaries (43–6013).
*** Mean hourly wage for Pharmacy Technicians (29–2052).

Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 8, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–14770 Filed 7–10–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1768]

Harmonizing Compendial Standards With Drug Application Approval Using the United States Pharmacopeial Convention Pending Monograph Process; 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 ''Harmonizing Compendial Standards with Drug Application Approval Using the USP Pending Monograph Process.'' This guidance assists applicants (or drug substance master file (MF) holders referenced in an application) in the

initiation of either revisions to an existing monograph(s) or development of a new monograph(s) under the United States Pharmacopeial Convention Pending Monograph Process (USP–PMP) during FDA's evaluation of a drug substance master file or drug product application. This guidance describes the process that allows for the revision of compendial standards that are harmonized with the approved quality and labeling requirements for a drug product application.

DATES: Submit either electronic or written comments on the draft guidance by September 9, 2019 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–2019–D–1768 for ''Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process.'' 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.

- 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.gpo.gov/fdsys/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.

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 Policy and Regulations Staff, HFV–6, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: Lana Bruney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4157, Silver Spring, MD 20993–0002, 240–402–3462; or Mai Huynh, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rm. E337, Rockville, MD 20855, 240–402–0669.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process.'' As part of the reauthorization of the Generic Drug User Fee Amendments (GDUFA II), FDA recommitted to promoting the efficiency and effectiveness of the application review process. Part of the application approval process includes compliance with the official compendium, the USP–NF (National Formulary), if applicable. This guidance assists applicants in the initiation of either revisions to an existing monograph(s) or development of a new monograph(s) under the USP–PMP during FDA's evaluation of a drug substance MF or drug product application.

A drug with a name recognized in the USP–NF must comply with compendial identity standards or the drug will be deemed adulterated, misbranded, or both (see section 501(b) and 502(e)(3)(b) and (g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(b) and 352(e)(3)(b) and (g)); and § 299.5(a) and (b) (21 CFR 299.5(a) and (b))). Such drugs must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs, or they will be deemed adulterated (see section 501(b) of the FD&C Act and § 299.5(c)). Before USP–PMP launched, if during the review of a new drug application (NDA), an abbreviated new drug application (ANDA), a new animal drug application (NADA), or an abbreviated new animal drug application (ANADA), it was clear that the proposed specifications would not comply with the current

monograph, approval of the application and patient access to the drug were delayed because the USP–NF standards development processes did not accept proposals from applicants requesting changes to compendial standards for products that were not currently approved by FDA. If a monograph needed to be revised to include the applicant's proposed specifications, there were no mechanisms to do this until after the application was approved. For approval, the product would have to be shown to meet the current monograph, at least for identity, and the product label would have to indicate differences from the monograph regarding strength, quality, or purity. Typically, the revised monograph would not become official for 6 months or more. The USP–PMP was created to address these issues.

Under the USP–PMP, applicants that have successfully filed an NDA, ANDA, NADA, or ANADA with FDA and are awaiting review and approval can propose revisions to an existing monograph or can propose the publication of a new monograph for an article that is not currently part of the official compendia. MF holders referenced in a successfully filed NDA, ANDA, NADA, or ANADA may also propose revisions to an existing monograph or propose publication of a new monograph for their drug substance. Immediately following FDA approval of a specific NDA, ANDA, NADA, or ANADA, USP will make available a revised monograph (or new monograph, as applicable) harmonized with the application's approved quality specifications. This process results in the creation of compendial standards that are harmonized with the quality specifications in an approved application. (Note: Initiation of the USP–PMP does not confer Agency acceptability of the compendial standards proposed for the product, nor preclude full application evaluation by the Agency; all applications will be subject to complete evaluation using current established review practices.)

This guidance details the Agency's expectations for applicants (and MF holders referenced by applications awaiting approval) who choose to use the USP–PMP. The document explains how applicants (and MF holders) should initiate the process, provides Agency recommendations, and addresses some common situations that may arise during use of the USP–PMP.

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 ''Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information relating to NDAs and ANDAs in 21 CFR part 314, including 21 CFR 314.50, 314.94, and 314.420, have been approved under OMB control number 0910–0001. The collections of information relating to NADAs in 21 CFR part 514, including 21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, and 558.5 have been approved under OMB control number 0910–0032. The collections of information relating to ANADAs in sections 512(b)(2) and (n)(1) of the FD&C Act (21 U.S.C. 360b(b)(2) and (n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, or https://www.regulations.gov.*

Dated: July 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14781 Filed 7–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0331]

Live Case Presentations During Investigational Device Exemption Clinical Trials; Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff; 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 entitled ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials.'' The purpose of this guidance is to provide institutional review boards (IRBs), industry, clinical investigators, and FDA staff with factors to consider when evaluating the appropriateness of a live case presentation within a clinical investigation conducted under an investigational device exemption (IDE) application. This document provides guidance on important information about a live case presentation that should be provided as part of an original IDE application or a supplement to an IDE application when requesting inclusion of a live case presentation during a clinical investigation.

DATES: The announcement of the guidance is published in the **Federal Register** on July 11, 2019.

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