maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the 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. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and 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In the **Federal Register** of February 1, 2023 (88 FR 6750), FDA published a notice announcing the availability of a draft guidance entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; International Council for Harmonisation.'' The notice gave interested persons an opportunity to submit comments by April 3, 2023.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in July 2024.

This guidance finalizes the draft guidance issued on February 1, 2023. The final guidance includes clarification on the scientific and technical aspects of study design and data analysis to support BE assessment for orally administered immediate-release solid oral dosage forms. The supplemental questions and answers document provides further clarification and examples of the technical aspects of the main guidance in order to effectively implement the guidance. The internationally harmonized guidance and questions and answers document aim to increase the efficiency of drug development and accelerate the availability of safe and effective orally administered immediate-release solid oral dosage forms.

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 ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms''. The guidance and supplemental questions and answers document 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. 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 21 CFR 314.94 for content and format for BE studies submitted under abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information for the implementation of improved quality and integrity of the study data approaches pertaining to good clinical practice have been approved under OMB control number 0910–0014.

III. Electronic Access

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

Dated: October 23, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25355 Filed 10–30–24; 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 Guidances; Revised Draft Guidances 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 additional revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, 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. The draft guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 30, 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 ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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: Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993–0002, 240–402–1062, *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. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on August 23, 2024 (89 FR 68162).

This notice announces revised draft product-specific guidances that are being posted on FDA's website for a subset of immediate-release oral drug products to reflect FDA's current thinking and to align the bioequivalence recommendations with the recently adopted International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use M13A guideline titled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' (October 2024). These revised product-specific guidances recommend that ANDA applicants conduct one bioequivalence study for products with a non-high risk of bioinequivalence due to food effect under either fasting or fed condition rather than conducting two bioequivalence studies: one BE study under fasting conditions, and one BE study under fed conditions. Other revisions, including revisions to align the recommendations in these PSGs with the recently adopted M13A guideline and editorial revisions, are incorporated as appropriate. FDA recommends that applicants consult the relevant product-specific guidance, in conjunction with general guidances on bioequivalence, when considering the design and conduct of studies supporting an evaluation of BE for immediate-release solid oral dosage forms.

II. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Abacavir sulfate
Abacavir sulfate; Dolutegravir sodium; Lamivudine (multiple reference listed drugs)
Abacavir sulfate; Lamivudine
Abacavir sulfate; Lamivudine; Zidovudine
Abemaciclib
Abrocitinib
Acalabrutinib
Acetaminophen; Aspirin; Caffeine
Acetaminophen; Benzhydrocodone hydrochloride
Acetaminophen; Butalbital; Caffeine; Codeine phosphate
Acetaminophen; Ibuprofen
Acetaminophen; Propoxyphene napsylate
Acetaminophen; Tramadol hydrochloride
Acetazolamide
Acetylcysteine
Acrivastine; Pseudoephedrine hydrochloride
Acyclovir (multiple reference listed drugs)
Adagrasib
Adefovir dipivoxil
Albuterol sulfate
Allopurinol; Lesinurad
Almotriptan malate
Alogliptin benzoate
Alogliptin benzoate; Metformin hydrochloride
Alogliptin benzoate; Pioglitazone hydrochloride
Alosetron hydrochloride
Alprazolam (multiple reference listed drugs)
Amantadine hydrochloride (multiple reference listed drugs)
Ambrisentan
Amifampridine phosphate
Amiloride hydrochloride
Aminocaproic acid
Amiodarone hydrochloride
Amitriptyline hydrochloride
Amitriptyline hydrochloride; Chlordiazepoxide
Amlodipine benzoate
Amlodipine besylate
Amlodipine besylate; Atorvastatin calcium
Amlodipine besylate; Benazepril hydrochloride
Amlodipine besylate; Celecoxib
Amlodipine besylate; Hydrochlorothiazide; Olmesartan medoxomil
Amlodipine besylate; Hydrochlorothiazide; Valsartan
Amlodipine besylate; Olmesartan medoxomil
Amlodipine besylate; Perindopril arginine
Amlodipine besylate; Valsartan
Amoxicillin (multiple reference listed drugs)
Amoxicillin; Clarithromycin; Vonoprazan fumarate
Amoxicillin; Clavulanate potassium (multiple reference listed drugs)
Amoxicillin; Vonoprazan fumarate
Amphetamine aspartate; Amphetamine sulfate; Dextroamphetamine saccharate; Dextroamphetamine sulfate
Anagrelide hydrochloride
Anastrozole
Apixaban
Apremilast
Aripiprazole (multiple reference listed drugs)
Armodafinil
Aspirin
Aspirin; Butalbital; Caffeine; Codeine phosphate
Atazanavir sulfate
Atazanavir sulfate; Cobicistat
Atenolol
Atenolol; Chlorthalidone
Atomoxetine hydrochloride
Atorvastatin calcium (multiple reference listed drugs)
Atorvastatin calcium; Ezetimibe
Atovaquone (multiple reference listed drugs)
Auranofin
Avanafil
Avatrombopag maleate
Axitinib
Azilsartan kamedoxomil
Azilsartan kamedoxomil; Chlorthalidone

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Azithromycin (multiple reference listed drugs)
Baclofen (multiple reference listed drugs)
Baloxavir marboxil (multiple reference listed drugs)
Baricitinib
Bedaquiline fumarate
Belumosudil mesylate
Bempedoic acid
Bempedoic acid; Ezetimibe
Benazepril hydrochloride
Benazepril hydrochloride; Hydrochlorothiazide
Benznidazole
Berotralstat hydrochloride
Bexagliflozin
Bicalutamide
Binimetinib
Bisoprolol fumarate
Bisoprolol fumarate; Hydrochlorothiazide
Boceprevir
Bosentan (multiple reference listed drugs)
Bosutinib monohydrate
Brexpiprazole
Brincidofovir
Brivaracetam
Bumetanide
Bupropion hydrochloride
Buspirone hydrochloride
Cabotegravir sodium
Calcium carbonate; Famotidine; Magnesium hydroxide
Canagliflozin
Canagliflozin; Metformin hydrochloride
Candesartan cilexetil
Candesartan cilexetil; Hydrochlorothiazide
Capmatinib hydrochloride
Carbidopa
Carbidopa; Entacapone; Levodopa
Carbidopa; Levodopa (multiple reference listed drugs)
Carglumic acid
Cariprazine hydrochloride
Carisoprodol
Carvedilol
Cefaclor
Cefadroxil/cefadroxil hemihydrate
Cefdinir (multiple reference listed drugs)
Cefditoren pivoxil
Cefixime (multiple reference listed drugs)
Cefpodoxime proxetil (multiple reference listed drugs)
Cefprozil (multiple reference listed drugs)
Cefuroxime axetil (multiple reference listed drugs)
Celecoxib; Tramadol hydrochloride
Cenobamate
Cephalexin (multiple reference listed drugs)
Ceritinib (multiple reference listed drugs)
Cetirizine hydrochloride (multiple reference listed drugs)
Cevimeline hydrochloride
Chenodiol
Chlordiazepoxide hydrochloride
Chlordiazepoxide hydrochloride; Clidinium bromide
Chlorothiazide
Chlorpheniramine maleate; Ibuprofen; Phenylephrine hydrochloride
Chlorpheniramine maleate; Ibuprofen; Pseudoephedrine hydrochloride
Chlorpromazine hydrochloride
Chlorthalidone (multiple reference listed drugs)
Chlorzoxazone
Cholic acid
Cimetidine
Cinacalcet hydrochloride
Ciprofloxacin
Ciprofloxacin hydrochloride
Citalopram hydrobromide (multiple reference listed drugs)
Clarithromycin (multiple reference listed drugs)
Clemastine fumarate (multiple reference listed drugs)
Clindamycin hydrochloride

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Clobazam (multiple reference listed drugs)
Clomiphene citrate
Clomipramine hydrochloride
Clonazepam (multiple reference listed drugs)
Clonidine hydrochloride
Clopidogrel bisulfate
Clorazepate dipotassium
Cobicistat
Cobimetinib fumarate
Colchicine (multiple reference listed drugs)
Crizotinib
Cyclobenzaprine hydrochloride
Cycloserine
Daclatasvir dihydrochloride
Dacomitinib
Dantrolene sodium
Dapagliflozin
Dapagliflozin; Saxagliptin hydrochloride
Daprodustat
Dapsone
Darolutamide
Darunavir (multiple reference listed drugs)
Dasatinib
Deferiprone
Deflazacort (multiple reference listed drugs)
Delafloxacin meglumine
Delavirdine mesylate
Desipramine hydrochloride
Desloratadine (multiple reference listed drugs)
Desmopressin acetate
Desogestrel; Ethinyl estradiol (multiple reference listed drugs)
Dexamethasone
Dexmethylphenidate hydrochloride
Dexmethylphenidate hydrochloride; Serdexmethylphenidate chloride
Dextromethorphan hydrobromide; Quinidine sulfate
Diazepam
Diazoxide
Dichlorphenamide
Diclofenac
Diclofenac potassium (multiple reference listed drugs)
Dicyclomine hydrochloride (multiple reference listed drugs)
Dienogest; Estradiol valerate
Diflunisal
Diphenhydramine citrate; Ibuprofen
Diphenhydramine hydrochloride
Diphenhydramine hydrochloride; Ibuprofen
Diphenhydramine hydrochloride; Naproxen sodium
Dipyridamole
Disopyramide phosphate
Disulfiram
Dofetilide
Dolasetron mesylate
Dolutegravir sodium (multiple reference listed drugs)
Dolutegravir sodium; Lamivudine
Dolutegravir sodium; Rilpivirine hydrochloride
Donepezil hydrochloride (multiple reference listed drugs)
Doxazosin mesylate
Doxepin hydrochloride (multiple reference listed drugs)
Doxycycline (multiple reference listed drugs)
Doxycycline calcium
Doxycycline hyclate (multiple reference listed drugs)
Dronedarone hydrochloride
Drospirenone
Drospirenone; Estetrol
Drospirenone; Estradiol
Drospirenone; Ethinyl estradiol (multiple reference listed drugs)
Drospirenone; Ethinyl estradiol; Levomefolate calcium
Droxidopa
Duvelisib
Elacestrant dihydrochloride
Eletriptan hydrobromide
Eliglustat tartrate

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Eltrombopag olamine (multiple reference listed drugs)
Eluxadoline
Empagliflozin
Empagliflozin; Linagliptin
Empagliflozin; Metformin hydrochloride
Emtricitabine
Emtricitabine; Rilpivirine hydrochloride; Tenofovir alafenamide fumarate
Emtricitabine; Rilpivirine hydrochloride; Tenofovir disoproxil fumarate
Emtricitabine; Tenofovir alafenamide fumarate
Emtricitabine; Tenofovir disoproxil fumarate
Enalapril maleate
Enasidenib mesylate
Entacapone
Eplerenone
Eprosartan mesylate
Eprosartan mesylate; Hydrochlorothiazide
Erdafitinib
Ertugliflozin; Metformin hydrochloride
Ertugliflozin; Sitagliptin phosphate
Erythromycin ethylsuccinate (multiple reference listed drugs)
Erythromycin ethylsuccinate; Sulfisoxazole acetyl
Escitalopram oxalate (multiple reference listed drugs)
Eslicarbazepine acetate
Estradiol
Estradiol; Norethindrone acetate
Estrogens, esterified
Eszopiclone
Ethacrynic acid
Ethambutol hydrochloride
Ethinyl estradiol; Ethynodiol diacetate
Ethinyl estradiol; Levonorgestrel (multiple reference listed drugs)
Ethinyl estradiol; Norethindrone (multiple reference listed drugs)
Ethinyl estradiol; Norethindrone acetate (multiple reference listed drugs)
Ethinyl estradiol; Norethindrone acetate; Ethinyl estradiol; Ferrous fumarate
Ethinyl estradiol; Norgestimate
Ethinyl estradiol; Norgestrel
Ethionamide
Ethosuximide
Etodolac (multiple reference listed drugs)
Exemestane
Ezetimibe
Ezetimibe; Simvastatin
Ezogabine
Famciclovir
Famotidine (multiple reference listed drugs)
Famotidine; Ibuprofen
Febuxostat
Fedratinib hydrochloride
Fenofibric acid
Fenoprofen calcium
Fexofenadine hydrochloride (multiple reference listed drugs)
Finasteride
Finerenone
Fingolimod hydrochloride
Fingolimod lauryl sulfate
Flavoxate hydrochloride
Flecainide acetate
Flibanserin
Fluconazole
Flucytosine
Fludrocortisone acetate
Fluoxetine hydrochloride (multiple reference listed drugs)
Fluoxetine hydrochloride; Olanzapine
Fluphenazine hydrochloride
Flutamide
Fluvastatin sodium
Fosamprenavir calcium
Fosinopril sodium
Fosinopril sodium; Hydrochlorothiazide
Frovatriptan succinate
Furosemide
Futibatinib

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Gabapentin (multiple reference listed drugs)
Galantamine hydrobromide
Ganaxolone
Ganciclovir
Gefitinib
Gemifloxacin mesylate
Gilteritinib fumarate
Glasdegib maleate
Glimepiride
Glimepiride; Pioglitazone hydrochloride
Glimepiride; Rosiglitazone maleate
Glipizide
Glipizide; Metformin hydrochloride
Glyburide (multiple reference listed drugs)
Glyburide; Metformin hydrochloride
Granisetron hydrochloride
Griseofulvin, microcrystalline; Griseofulvin, microsize
Guanfacine hydrochloride
Haloperidol
Hydralazine hydrochloride; Isosorbide dinitrate
Hydrochlorothiazide (multiple reference listed drugs)
Hydrochlorothiazide; Irbesartan
Hydrochlorothiazide; Lisinopril
Hydrochlorothiazide; Losartan potassium
Hydrochlorothiazide; Metoprolol tartrate
Hydrochlorothiazide; Olmesartan medoxomil
Hydrochlorothiazide; Quinapril hydrochloride
Hydrochlorothiazide; Spironolactone
Hydrochlorothiazide; Triamterene (multiple reference listed drugs)
Hydrochlorothiazide; Valsartan
Hydrocodone bitartrate; Ibuprofen
Hydrocortisone
Hydromorphone hydrochloride
Hydroxychloroquine sulfate
Hydroxyzine pamoate (multiple reference listed drugs)
Ibrexafungerp citrate
Ibrutinib (multiple reference listed drugs)
Ibuprofen (multiple reference listed drugs)
Ibuprofen sodium
Ibuprofen; Phenylephrine hydrochloride
Ibuprofen; Pseudoephedrine hydrochloride (multiple reference listed drugs)
Icosapent ethyl
Idelalisib
Iloperidone
Imipramine pamoate
Indapamide
Indinavir sulfate
Indomethacin (multiple reference listed drugs)
Irbesartan
Isavuconazonium sulfate
Isocarboxazid
Isosorbide dinitrate (multiple reference listed drugs)
Isradipine
Istradefylline
Ivabradine hydrochloride
Ketoconazole
Ketoprofen
Ketorolac tromethamine
Lacosamide
Lamivudine (multiple reference listed drugs)
Lamivudine; Tenofovir disoproxil fumarate (multiple reference listed drugs)
Lamivudine; Zidovudine
Lamotrigine (multiple reference listed drugs)
Larotrectinib sulfate
Lasmiditan succinate
Leflunomide
Lemborexant
Lenalidomide
Lesinurad
Letermovir
Letrozole
Letrozole; Ribociclib succinate

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Leucovorin calcium
Levetiracetam (multiple reference listed drugs)
Levocarnitine
Levocetirizine dihydrochloride (multiple reference listed drugs)
Levofloxacin
Levonorgestrel
Levorphanol tartrate
Linagliptin
Linagliptin; Metformin hydrochloride
Linezolid (multiple reference listed drugs)
Lisdexamfetamine dimesylate (multiple reference listed drugs)
Lisinopril
Lofexidine hydrochloride
Loperamide hydrochloride (multiple reference listed drugs)
Loperamide hydrochloride; Simethicone
Loratadine (multiple reference listed drugs)
Lorazepam
Lumateperone tosylate
Lurasidone hydrochloride
Lusutrombopag
Macitentan
Maraviroc
Maribavir
Mavacamten
Mecamylamine hydrochloride
Medroxyprogesterone acetate
Mefenamic acid
Megestrol acetate
Meloxicam (multiple reference listed drugs)
Memantine hydrochloride
Mesna
Mestranol; Norethindrone
Metformin hydrochloride
Metformin hydrochloride; Pioglitazone hydrochloride
Metformin hydrochloride; Repaglinide
Metformin hydrochloride; Sitagliptin phosphate
Methazolamide
Methenamine hippurate
Methimazole
Methoxsalen (multiple reference listed drugs)
Methsuximide
Methylergonovine maleate
Methylphenidate hydrochloride (multiple reference listed drugs)
Methylprednisolone
Methyltestosterone
Metoclopramide hydrochloride (multiple reference listed drugs)
Metolazone
Metoprolol tartrate
Metyrosine
Mexiletine hydrochloride
Midodrine hydrochloride
Miglustat
Milnacipran hydrochloride
Minocycline hydrochloride (multiple reference listed drugs)
Minoxidil
Mirtazapine (multiple reference listed drugs)
Mitapivat sulfate
Mobocertinib succinate
Modafinil
Molindone hydrochloride
Montelukast sodium (multiple reference listed drugs)
Morphine sulfate
Moxidectin
Moxifloxacin hydrochloride
Mycophenolate mofetil (multiple reference listed drugs)
Nabumetone
Nadolol
Naldemedine tosylate
Naltrexone hydrochloride
Naproxen (multiple reference listed drugs)
Naproxen sodium (multiple reference listed drugs)
Naratriptan hydrochloride

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Nateglinide
Nebivolol hydrochloride
Nebivolol hydrochloride; Valsartan
Neratinib maleate
Netupitant; Palonosetron hydrochloride
Nevirapine (multiple reference listed drugs)
Nicardipine hydrochloride
Nimodipine
Nitisinone (multiple reference listed drugs)
Nitrofurantoin
Nitrofurantoin, macrocrystalline
Nitrofurantoin; Nitrofurantoin, macrocrystalline
Norethindrone (multiple reference listed drugs)
Norethindrone acetate
Nortriptyline hydrochloride
Obeticholic acid
Olanzapine (multiple reference listed drugs)
Olanzapine; Samidorphan l-malate
Olmesartan medoxomil
Omaveloxolone
Omega-3-acid ethyl esters type a
Ondansetron
Ondansetron hydrochloride
Oseltamivir phosphate (multiple reference listed drugs)
Osilodrostat phosphate
Osimertinib mesylate
Ospemifene
Oteseconazole
Oxaprozin
Oxazepam
Oxcarbazepine (multiple reference listed drugs)
Oxybutynin chloride
Oxycodone hydrochloride (multiple reference listed drugs)
Oxymetholone
Ozanimod hydrochloride
Pacritinib citrate
Palbociclib
Palonosetron hydrochloride
Panobinostat lactate
Paroxetine hydrochloride
Paroxetine mesylate (multiple reference listed drugs)
Pemigatinib
Penbutolol sulfate
Penicillin v potassium
Perampanel (multiple reference listed drugs)
Perindopril erbumine
Perphenazine
Phenelzine sulfate
Phentermine hydrochloride
Pilocarpine hydrochloride
Pimavanserin tartrate (multiple reference listed drugs)
Pimozide
Pindolol
Pioglitazone hydrochloride
Pirfenidone (multiple reference listed drugs)
Piroxicam
Pitavastatin calcium
Pitavastatin magnesium
Pitavastatin sodium
Pitolisant hydrochloride
Pomalidomide
Ponesimod
Pramipexole dihydrochloride
Prasugrel hydrochloride
Pravastatin sodium
Praziquantel
Prazosin hydrochloride
Prednisolone
Prednisolone acetate
Prednisolone sodium phosphate
Pregabalin
Primaquine phosphate

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Prochlorperazine maleate
Promethazine hydrochloride
Propafenone hydrochloride
Propranolol hydrochloride
Propylthiouracil
Protriptyline hydrochloride
Prucalopride succinate
Pyrazinamide
Pyridostigmine bromide
Pyrimethamine
Quetiapine fumarate
Quinapril hydrochloride
Raloxifene hydrochloride
Ramelteon
Ramipril (multiple reference listed drugs)
Ranitidine hydrochloride (multiple reference listed drugs)
Relugolix
Repaglinide
Reserpine
Ribavirin (multiple reference listed drugs)
Ribociclib succinate
Rifapentine
Rilpivirine hydrochloride
Rimegepant sulfate
Riociguat
Risperidone (multiple reference listed drugs)
Rivastigmine tartrate
Rizatriptan benzoate (multiple reference listed drugs)
Roflumilast
Rolapitant hydrochloride
Ropinirole hydrochloride
Rosiglitazone maleate
Rosuvastatin calcium
Rufinamide (multiple reference listed drugs)
Ruxolitinib phosphate
Sacubitril; Valsartan
Safinamide mesylate
Sapropterin dihydrochloride
Sarecycline hydrochloride
Saxagliptin hydrochloride
Selegiline hydrochloride (multiple reference listed drugs)
Selexipag
Selpercatinib
Sertraline hydrochloride (multiple reference listed drugs)
Sibutramine hydrochloride
Sildenafil citrate (multiple reference listed drugs)
Silodosin
Simvastatin (multiple reference listed drugs)
Simvastatin; Sitagliptin phosphate
Siponimod
Sitagliptin phosphate
Sodium phenylbutyrate (multiple reference listed drugs)
Sodium phenylbutyrate; Taurursodiol
Sofosbuvir
Solifenacin succinate
Solriamfetol hydrochloride
Sotalol hydrochloride (multiple reference listed drugs)
Sotorasib
Sparsentan
Spironolactone (multiple reference listed drugs)
Stavudine
Stiripentol (multiple reference listed drugs)
Succimer
Sulfadiazine
Sulfamethoxazole; Trimethoprim (multiple reference listed drugs)
Sumatriptan succinate
Tadalafil
Tafenoquine succinate (multiple reference listed drugs)
Tamoxifen citrate
Tapentadol hydrochloride
Tasimelteon
Tecovirimat

TABLE 1—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Tedizolid phosphate
Telbivudine
Telithromycin
Telotristat etiprate
Temazepam
Tenofovir alafenamide fumarate
Tenofovir disoproxil fumarate (multiple reference listed drugs)
Tepotinib hydrochloride
Terazosin hydrochloride
Terbinafine hydrochloride (multiple reference listed drugs)
Terbutaline sulfate
Teriflunomide
Testosterone undecanoate
Tetrabenazine
Tetracycline hydrochloride
Thioridazine hydrochloride
Thiothixene
Tiagabine hydrochloride
Ticagrelor
Ticlopidine hydrochloride
Timolol maleate
Tivozanib hydrochloride
Tizanidine hydrochloride
Tofacitinib citrate
Tolcapone
Tolterodine tartrate
Topiramate (multiple reference listed drugs)
Toremifene citrate
Torsemide (multiple reference listed drugs)
Trandolapril
Tranylcypromine sulfate
Trazodone hydrochloride
Triamterene
Triazolam
Triclabendazole
Trimethoprim
Trimipramine maleate
Ubrogepant
Ulipristal acetate
Uridine triacetate
Ursodiol (multiple reference listed drugs)
Valacyclovir hydrochloride
Valbenazine tosylate
Valganciclovir hydrochloride
Valsartan
Vandetanib
Vardenafil hydrochloride (multiple reference listed drugs)
Varenicline tartrate
Vericiguat
Vibegron
Vilazodone hydrochloride
Vismodegib
Vorapaxar sulfate
Vortioxetine hydrobromide
Voxelotor (multiple reference listed drugs)
Zalcitabine
Zaleplon
Zidovudine (multiple reference listed drugs)
Zileuton
Ziprasidone hydrochloride (multiple reference listed drugs)
Zolmitriptan (multiple reference listed drugs)
Zolpidem tartrate
Zonisamide

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. 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.

III. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

IV. 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: October 24, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25391 Filed 10–30–24; 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: Maternal and Child Health Jurisdictional Survey Instrument for the Title V Maternal and Child Health Block Grant Program

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 30, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Maternal and Child Health (MCH) Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906–0042—Revision

Abstract: The purpose of the Title V MCH Services Block Grant is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating Federal/State partnerships that provide each State/jurisdiction with needed flexibility to respond to its individual MCH population needs. Unique to the MCH Block Grant is a commitment to performance accountability, while assuring State flexibility. Utilizing a three-tiered national performance measure framework, which includes National Outcome Measures, National Performance Measures, and Evidence-Based and -Informed Strategy Measures, State MCH Block Grant programs report annually on their performance relative to the selected national performance and outcome measures. Such reporting enables the State and Federal program offices to assess the progress achieved in key MCH priority areas and to document MCH Block Grant program accomplishments.

By legislation (section 505(a) and 506(a) of title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH health agency. In establishing State reporting requirements, HRSA considers the availability of national data from Federal agencies. Data for the National Performance and Outcome Measures are pre-populated for States in the Title V Information System. Such national data sources often do not include data from the title V jurisdiction grantees, with the exception of the District of Columbia. As a result, the eight remaining jurisdictions (*i.e.,* American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, Puerto Rico, the Republic of the Marshall Islands, the Federated States of Micronesia, and U.S. Virgin Islands) have limited access to significant data and MCH indicators, with limited resources for collecting these data.

Sponsored by HRSA, the MCH Jurisdictional Survey is designed to produce data on the physical and emotional health of mothers and children under 18 years of age in the following eight jurisdictions—American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, Puerto Rico, the Republic of the Marshall Islands, the Federated States of Micronesia, and U.S. Virgin Islands. More specifically, the MCH Jurisdictional Survey collects information on factors related to the well-being of children, including health status, visits to health care providers, health care costs, and health insurance coverage. In addition, the MCH Jurisdictional Survey collects information on factors related to the well-being of mothers, including health risk behaviors, health conditions, and preventive health practices. Collecting these data will enable the jurisdictions to meet Federal performance reporting requirements and demonstrate the impact of MCH Block Grant funding on MCH outcomes.

The MCH Jurisdictional Survey was designed based on information-gathering activities with title V leadership and program staff in the jurisdictions, Federal experts, and organizations with relevant data collection experience. Survey items are based on the National Survey of Children's Health; the Behavioral Risk Factor Surveillance System; the Youth Behavior Surveillance System; and selected other Federal studies. The Survey is designed as a core questionnaire to be administered across all jurisdictions with a supplemental set of survey questions customized to the needs of each jurisdiction.

The MCH Jurisdictional Survey has been conducted annually since 2019, with several modifications to address emerging issues and challenges related to survey questions and methods. The 2022 extension (ICR 202203–0906–002) enhanced the detail in collecting demographic data through race and ethnicity survey questions in response to jurisdictional feedback. Since the