of project management staff, or to the division director of the appropriate product office within CBER, but only after first contacting the appropriate review division or the Biosimilars Program staff, CDER, Office of New Drugs to determine to whom the request should be directed, how it should be submitted, and the appropriate format for the request and to arrange for confirmation of receipt of the request. We recommend the following information be included in the meeting request:

1. Application number (if previously assigned),
2. development-phase code name of the product (if prelicensure),
3. proper name (if post licensure),
4. structure (if applicable),
5. proper and proprietary names of the reference product,
6. proposed indication(s) or context of product development,
7. pediatric study plans, if applicable,
8. human factors engineering plan, if applicable,
9. combination product information (*e.g.,* constituent parts, including details of the device constituent part, intended packaging, planned human factors studies), if applicable,
10. meeting type being requested (the rationale for requesting the meeting type should be included),
11. proposed format of the meeting (face to face, tele-conference/video-conference/WRO),
12. a brief statement of the purpose of the meeting, including a brief background of the issues underlying the agenda. It can also include a brief summary of completed or planned studies and clinical trials or data the sponsor or applicant intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in the overall development plans.
13. a list of specific objectives/outcomes expected from the meeting,
14. a proposed agenda, including times required for each agenda item,
15. a list of questions grouped by discipline and a brief explanation of the context and purpose of each question,
16. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and any consultants and interpreters,
17. a list of FDA staff, if known, or disciplines asked to participate in the requested meeting, and
18. suggested dates and times for the meeting.

We use the information to determine the utility of the meeting, to identify FDA staff necessary to discuss proposed agenda items, and to schedule the meeting.

B. Information Package

We recommend that a sponsor or applicant submit a meeting package to the appropriate review division with the meeting request and that the following information be included in the package:

1. Application number (if previously assigned),
2. development-phase code name of product (if pre-licensure) or proper name (if post-licensure),
3. structure (if applicable),
4. proprietary and proper names of the reference product,
5. proposed indication(s) or context of product development,
6. dosage form, route of administration, dosing regimen (frequency and duration), and presentation(s),
7. pediatric study plans, if applicable,
8. human factors engineering plan, if applicable,
9. combination product information, if applicable,
10. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and any consultants and interpreters,
11. background that includes a brief history of the development program and the status of product development (*e.g.,* chemistry, manufacturing, and controls; nonclinical; and clinical, including any development outside the United States, as applicable),
12. a brief statement summarizing the purpose of the meeting,
13. the proposed agenda, and
14. a list of questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question, and data to support discussion organized by discipline and question.

The purpose of the meeting package is to provide FDA staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

BsUFA information collection	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER Meeting Requests	36	2.5	89	15	1,335
CDER Information Packages	29	2.2	64	30	1,920
CBER Meeting Requests	2	1	2	15	30
CBER Information Packages	2	2	4	30	120
Total					3,405

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

Since last OMB review of the information collection we have increased our burden estimate by 95 annual responses and 1,965 annual hours. This adjustment corresponds with an increase in submissions received by the Agency over the past 3 years.

Dated: November 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25328 Filed 11–21–19; 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; Draft and 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 draft and revised draft product-specific guidances. The 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 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 January 21, 2020 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.

- 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 guidances 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 documents.

FOR FURTHER INFORMATION CONTACT: Wendy Good, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 240–402–1146.

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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

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 September 17, 2019. This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances are Available

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

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

Active ingredient(s)
Acetaminophen; Benzhydrocodone hydrochloride.
Betamethasone dipropionate; Calcipotriene.
Cefaclor.
Chlorzoxazone (multiple reference listed drugs).
Copper.
Dolutegravir sodium; Rilpivirine hydrochloride.
Doxycycline hyclate.
Encorafenib.
Fluorometholone acetate.
Indocyanine green.
Isoniazid; Pyrazinamide; Rifampin.
Isosorbide dinitrate.
Ketoprofen.
Latanoprost; Netarsudil dimesylate.
Lidocaine.
Lorlatinib.
Lovastatin.
Lutetium dotatate Lu-177.
Medroxyprogesterone acetate.
Meloxicam.
Mifepristone.
Migalastat hydrochloride.
Omadacycline tosylate (multiple reference listed drugs).
Oxymetazoline hydrochloride.
Pimavanserin tartrate.
Sumatriptan succinate.
Tetracaine hydrochloride.
Timolol maleate.

III. 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 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Adapalene (multiple reference listed drugs).
Adapalene; Benzoyl peroxide (multiple reference listed drugs).
Azacitidine.
Baclofen.
Benzoyl peroxide; Clindamycin phosphate (multiple reference listed drugs).
Benzoyl peroxide; Erythromycin (multiple reference listed drugs).
Capsaicin.
Cariprazine hydrochloride.
Clindamycin phosphate (multiple reference listed drugs).
Clindamycin phosphate; Tretinoin.
Clonidine.
Clonidine hydrochloride.
Dapsone (multiple reference listed drugs).
Diclofenac epolamine.
Didanosine.
Disopyramide phosphate.
Doxepin hydrochloride.
Estradiol (multiple reference listed drugs).
Estradiol; Levonorgestrel.
Estradiol; Norethindrone acetate.
Ethinyl estradiol; Norelgestromin.
Fentanyl.
Flavoxate hydrochloride.
Granisetron.
Indapamide.
Lidocaine.
Lithium carbonate.
Menthol; Methyl salicylate.
Metformin hydrochloride; Repaglinide.
Methylphenidate.
Mifepristone.
Molindone hydrochloride.
Mycophenolate mofetil.
Nicotine.
Nitrofurantoin, Macrocrystalline.
Nitrofurantoin; Nitrofurantoin, Macrocrystalline.
Nitroglycerin (multiple reference listed drugs).
Oxybutynin (multiple reference listed drugs).
Pimecrolimus.
Prednisolone sodium phosphate.
Rivastigmine.
Roflumilast.
Rotigotine.
Scopolamine.
Selegiline.
Sulfacetamide sodium.
Sulfadiazine.
Tazarotene (multiple reference listed drugs).
Terazosin hydrochloride.
Testosterone.
Tinidazole.
Tipiracil hydrochloride; Trifluridine.
Tretinoin (multiple reference listed drugs).

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.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidances at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25326 Filed 11–21–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0736]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on our use of a tracking network to collect and share safety information about animal food from Federal, State, and Territorial Agencies.

DATES: Submit either electronic or written comments on the collection of information by January 21, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 21, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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,