

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal MIECHV Form 1 .....	25	1	500	12,500

*Estimated Total Annual Burden Hours: 12,500.*

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-10167 Filed 5-15-19; 8:45 am]

BILLING CODE 4184-77-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**DATES:** Submit either electronic or written comments on the draft guidance by July 15, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-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://](https://www.regulations.gov)

[www.regulations.gov](http://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 February 25, 2019 (84 FR 6005). 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

Acetaminophen; Codeine phosphate  
Apalutamide  
Beclomethasone dipropionate  
Benoxinate hydrochloride; Fluorescein sodium  
Bictegravir sodium; Emtricitabine; Tenofovir alafenamide fumarate  
Brimonidine tartrate  
Budesonide  
Chlorpheniramine maleate; Ibuprofen; Pseudoephedrine hydrochloride  
Cyclosporine  
Desloratadine; Pseudoephedrine sulfate  
Desmopressin acetate  
Efavirenz; Lamivudine; Tenofovir disoproxil fumarate (multiple Reference Listed Drugs)  
Eravacycline dihydrochloride  
Estradiol; levonorgestrel  
Fluticasone furoate  
Fluticasone propionate  
Fluticasone propionate; Salmeterol xinafoate  
Fosnetupitant chloride hydrochloride; Palonosetron hydrochloride  
Halcinonide  
Lamivudine; Tenofovir disoproxil fumarate  
Naproxen  
Omeprazole magnesium  
Primidone  
Timolol maleate  
Tobramycin

**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

Azelaic acid (multiple Reference Listed Drugs)  
Betaxolol hydrochloride  
Brimonidine tartrate; Brinzolamide  
Brinzolamide  
Fosfomycin tromethamine  
Ivermectin  
Methylprednisolone  
Prednisolone acetate  
Tofacitinib citrate

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. These guidances are not subject to Executive Order 12866.

**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: May 13, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990-0458 Revision]

**Agency Information Collection Request; 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed revision of a collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 17, 2019.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier OS-0990-0458 Revision, and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any