agencies to provide services in intergovernmental cases.

Respondents: All state and tribal CSE agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Intergovernmental Reference Guide: State Profile Guidance—(States and Territories)	54	18	0.3	291.6
Intergovernmental Reference Guide: Tribal Profile Guidance	62	18	0.3	334.8
Total				626.4

Estimated Total Annual Burden Hours: 626.4 hours.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. Email address *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and, (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Report Clearance Officer.

[FR Doc. 2017–28443 Filed 1–3–18; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6854]

Good Abbreviated New Drug Application Submission Practices; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Good ANDA Submission Practices.'' This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs). This draft guidance highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA. It also makes recommendations to applicants on how to avoid these deficiencies with the goal of minimizing the number of review cycles necessary for approval.

DATES: Submit either electronic or written comments on the draft guidance by March 5, 2018 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–2017–D–6854 for ''Good ANDA Submission Practices.'' 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. 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: Michelle Sollenberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993–0002, 240–402–0981.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Good ANDA Submission Practices.'' This draft guidance is intended to assist applicants preparing to submit ANDAs to FDA. It highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA. This draft guidance also makes recommendations to applicants on how to avoid these deficiencies so that applicants can submit ANDAs that may be approved in the first review cycle. This draft guidance has been developed as part of FDA's ''Drug Competition Action Plan,'' which, in coordination with the Generic Drug User Fee Amendments (GDUFA I and II) (Pub. L. 112–144 and Pub. L. 115–52, respectively) and other FDA activities, is expected to increase competition in the market for prescription drugs, facilitate entry of high-quality and affordable generic drugs, and improve public health.

In conjunction with this draft guidance, FDA is issuing a *Good ANDA Assessment Practices Manual of Policies and Procedures,* which establishes good ANDA assessment practices for the Office of Generic Drugs and the Office of Pharmaceutical Quality to increase their operational efficiency and effectiveness. This draft guidance and the *Manual of Policies and Procedures* are intended to build upon the success of the GDUFA program and to help reduce the number of review cycles for an ANDA to attain approval.

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 good ANDA submission practices. 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 draft 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 in the draft guidance have been approved under OMB control numbers 0910–0001 and 0910–0786.

III. Electronic Access

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

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28435 Filed 1–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2017–N161; FXES11140100000–189–FF01E00000]

Proposed Graysmarsh Safe Harbor Agreement for the Taylor's Checkerspot Butterfly, Clallam County, Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: Graysmarsh, LLC, hereafter referred to as the applicant, has applied to the U.S. Fish and Wildlife Service (Service, us) for an enhancement of survival permit (permit) pursuant to the Endangered Species Act of 1973, as amended. The permit application includes a draft safe harbor agreement (SHA). The permit would authorize incidental take of the endangered Taylor's checkerspot butterfly. We have prepared a draft environmental action statement (EAS) for our preliminary determination that the SHA and permit decision may be eligible for categorical exclusion under the National Environmental Policy Act (NEPA). We invite the public to review and comment on the permit application, draft SHA, and the draft EAS.

DATES: To ensure consideration, please send your written comments by February 5, 2018.

ADDRESSES: You may view or download copies of the draft SHA, and draft EAS and obtain additional information on the internet at *http://www.fws.gov/wafwo/* or obtain hard copies or a CD–ROM by calling the phone number listed below. You may submit comments or requests for more information by any of the following methods:

- *Email: wfwocomments@fws.gov.* Include ''Graysmarsh SHA'' in the subject line of the message.
- *U.S. Mail:* Mark Ostwald, U.S. Fish and Wildlife Service, Washington Fish and Wildlife Office, 510 Desmond Drive, Southeast, Suite 102, Lacey, WA 98503.
- *In-Person Drop-off, Viewing, or Pickup:* Call 360–753–9564 to make an appointment (necessary for viewing/pickup only) during regular business