

not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

**III. Registration Instructions**

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), and email address. You will receive a registration confirmation with instructions for your participation at the virtual public meeting.

**IV. Collection of Information**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Acting Director for the Center for Clinical Standards and Quality, at the Centers for Medicare & Medicaid Services, Jean Moody-Williams, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the **Federal Register Liaison**, to electronically sign this document for purposes of publication in the **Federal Register**.

**Authority:** 5 U.S.C. App. 2, section 10(a).

Dated: June 8, 2020.

**Evell J. Barco Holland,**

*Federal Register Liaison, Department of Health and Human Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Administration for Native Americans (ANA) Ongoing Progress Report (OPR) and Objective Work Plan (OWP)**

**AGENCY:** Administration for Native Americans, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families' (ACF) Administration for Native Americans (ANA) is requesting a revision to the information collection: Ongoing Progress Report (OPR) and the Objective Work Plan (OWP) (OMB #0970-0452). Changes are proposed to reduce the burden on the public by combining ANA's Annual Data Report (OMB #0970-0475) with the OPR.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Alternatively, copies can also be obtained by writing to the Administration for Children and

Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* Content changes are being made to the currently approved OPR. ANA will continue to use the currently approved OPR with minimal changes to the instructions for the remainder of fiscal year (FY) 2020 and will use the modified OPR beginning FY 2021. The modified OPR combines ANA's Annual Data Report (OMB #0970-0475) with the OPR. The information in the OPR is collected on a semi-annual basis to monitor the performance of grantees and better gauge grantee progress.

The OPR information collection is conducted in accordance with Sec. 811 [42 U.S.C. 2992] of the Native American Programs Act and will allow ANA to report quantifiable results across all program areas. It also provides grantees with parameters for reporting their progress and helps ANA better monitor and determine the effectiveness of their projects.

There are no changes proposed to the OWP. The OWP information collection is conducted in accordance with 42 U.S.C. of the Native American Programs Act of 1972, as amended. This collection is necessary to evaluate applications for financial assistance and determine the relative merits of the projects for which such assistance is requested, as set forth in Sec. 806 [42 U.S.C. 2991d-1](a)(1).

*Respondents:* Federally and state-recognized tribes, Native Pacific Islanders, Tribal Colleges and Universities, native non-profits, and consortia.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours*
Objective Work Plan .....	300	1	3	900	300
Ongoing Progress Report FY 2020 .....	200	2	1	400	133
Ongoing Progress Report FY 2021—Exp. Date .....	200	4	2	1600	533

\*Burden is annualized over the three year approval period.

*Estimated Total Annual Burden Hours:* 966.

*Comments:* 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.

**Authority:** Sec. 806 [42 U.S.C. 2991d–1](a)(1) and Sec. 811 [42 U.S.C. 2992].

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020–12739 Filed 6–11–20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–4533]

#### Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that published in the **Federal Register** on November 20, 2019. In that notice, FDA requested comments on the draft guidance for industry (GFI) #256 entitled “Compounding Animal Drugs from Bulk Drug Substances.” FDA is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is further extending the comment period on the document published November 20, 2019 (84 FR 64085), which was reopened in a document published February 20, 2020 (85 FR 9783). Submit either electronic or written comments on the draft guidance by October 15, 2020, to ensure that the Agency considers your comments 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–2018–D–4533 for “Compounding Animal Drugs From Bulk Drug Substances.” 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.

**FOR FURTHER INFORMATION CONTACT:** Eric Nelson, Division of Compliance (HFV–230), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, [cvmcompliance@fda.hhs.gov](mailto:cvmcompliance@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 20, 2019, FDA published a notice announcing the availability of draft GFI #256 entitled “Compounding Animal Drugs From Bulk Drug Substances” with a 90-day comment period. We requested comments on the draft guidance with respect to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment option exists.

Interested persons were originally given until February 18, 2020, to comment on the draft guidance. The Agency received requests to allow interested persons additional time to comment. The requests conveyed concern that the initial 90-day comment period did not allow sufficient time to develop a comprehensive response. FDA considered these requests and reopened the comment period for an additional 120 days, until June 17, 2020 (85 FR 9783).

Since then, FDA has received additional requests to further extend the comment period. FDA has considered the requests and is extending the comment period for the notice of availability for another 120 days, until October 15, 2020. The Agency believes that a further extension of 120 days allows adequate time for interested persons to submit comments.