

collection under 45 CFR 1355.41–.47 to be implemented October 1, 2019. Commenters addressed support for the collection of information under the Indian Child Welfare Act and other areas covered by the new requirements. ACF received no comment on the specific burden hours for the existing AFCARS requirements undergoing renewal.

AFCARS is mandated by 42 U.S.C. 679. The regulation at 45 CFR 1355.40 and the appendices to 45 CFR 1355 set

forth the requirements of section 479 of the Social Security Act for the collection of uniform, reliable information on children who are under the responsibility of the State or Tribal title IV–B/IV–E agency for placement, care, and adoption. The AFCARS requirements under 45 CFR 1355.40 have been in effect since October 1, 1993 for States. In 2009, section 479B(b) of the Act was enacted authorizing direct Federal funding of Indian Tribes, Tribal organizations, and Tribal

consortia that choose to operate a foster care, adoption assistance and, at Tribal option, a kinship guardianship assistance program under title IV–E of the Act. The data collected informs State/Tribal/Federal policy decisions, program management, and responses to Congressional and Departmental inquiries.

*Respondents:* Title IV–E State and Tribal Child Welfare Agencies.

#### ESTIMATED TOTAL ANNUAL BURDEN HOURS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS .....	59	2	2,188	258,215
Estimated Total Annual Burden Hours .....	.....	.....	.....	258,215

*Additional Information:* Copies of the regulation containing the data elements 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 Jones,**

*ACF/OPRE Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA–2016–D–1229]

##### Current Good Manufacturing Practice Requirements for Food for Animals; 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 guidance for industry #235 entitled “Current Good Manufacturing Practice Requirements for Food for Animals.” This guidance helps domestic and foreign facilities that are required to register as food facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) determine whether and how they need to comply with the current good manufacturing practice requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule.

**DATES:** The announcement of the guidance is published in the **Federal Register** on October 20, 2017.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2016–D–1229 for “Current Good Manufacturing Practice Requirements

for Food for Animals.” 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 office 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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246, [Jenny.Murphy@fda.hhs.gov](mailto:Jenny.Murphy@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of August 25, 2016 (81 FR 58519), FDA published the notice of availability for a draft guidance entitled “Current Good Manufacturing Practice Requirements for Food for Animals,” giving interested persons until November 23, 2016, to comment on the draft guidance. FDA received comments on the draft guidance and those comments were considered as the guidance was finalized. Changes made include additional explanation and examples and the inclusion of a part 507 (21 CFR part 507) Current Good Manufacturing Practice (CGMP) Self-Assessment Tool in Appendix B to assist facilities in reviewing the implementation of CGMP requirements at their facility. Information regarding human food by-products for use as food for animals was removed; this information is contained in draft GFI #239, entitled “Human Food By-Products for Use as Animal Food” (81 FR 58521, August 25, 2016). In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 2016.

**II. Significance of Guidance**

This level 1 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 current good manufacturing practice requirements for food for animals. 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 guidance is not subject to Executive Order 12866.

**III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These 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. 3501–3520). The collections of information in part 507 have been approved under OMB control number 0910–0789.

**IV. Electronic Access**

Persons with access to the internet may obtain the guidance at either

<https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: October 16, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA–2007–D–0369]**

**Product-Specific Guidances for Salmeterol Xinafoate and Fluticasone Propionate; 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 three draft guidances for industry on generic salmeterol xinafoate inhalation powder, fluticasone propionate inhalation aerosol, and fluticasone propionate inhalation powder, entitled “Draft Guidance on Salmeterol Xinafoate” and “Draft Guidance on Fluticasone Propionate.” The guidances, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for salmeterol xinafoate inhalation powder, fluticasone propionate inhalation aerosol, and fluticasone propionate inhalation powder.

**DATES:** Submit either electronic or written comments on the draft guidances by December 19, 2017 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