

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.

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: Dorothy Bailey, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0565, dorothy.bailey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 15, 2020 (85 FR 42876), FDA published the notice of availability for draft GFI #61 entitled “Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for

Minor Uses and for Minor Species” giving interested persons until November 12, 2020, to comment on the draft guidance. In response to a request for an extension, the comment period was extended to January 11, 2021 (85 FR 71659). FDA received 14 comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the final guidance include the following:

- In our draft guidance we referred to Minor Use Determinations. Our experience has shown that our stakeholders frequently confuse “MUMS Determination” with “MUMS Designation.” Therefore, the final guidance substitutes the word “Assessment” for the word “Determination.”

- Section XII.C.3.a.i. “Anthelmintics and Ectoparasiticides for Terrestrial Minor Species” has been added to the final guidance in response to comments received requesting additional detail on this subject. This section also references the relevant “International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)” guidance.

- CVM received many comments pertaining to aquaculture species grouping. Due to the complexity of this topic, CVM has removed examples of aquaculture species groupings in the final guidance. We continue to consider this topic and intend to work with individual drug sponsors wishing to use species groupings for new animal drug approvals to identify an appropriate species grouping strategy and subsequent data needs for specific projects.

In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated July 2020.

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 “Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.” 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to

review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; the collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0284; and the collections of information in 21 CFR part 516 have been approved under OMB control numbers 0910–0605.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28287 Filed 12–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–N–1157; FDA–2022–D–0109; FDA–2020–N–0908; FDA–2022–D–0814; FDA–2022–D–0745; FDA–2023–N–1006; FDA–2023–N–1053; FDA–2023–N–2286; FDA–2023–N–1661; FDA–2013–N–1119; FDA–2023–N–2986; FDA–2009–N–0582; FDA–2023–N–1272; FDA–2023–N–2030; FDA–2023–N–1189]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting

statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct

or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1.—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed	0910–0891	9/30/2026
Medical Devices—Voluntary Improvement Program	0910–0922	9/30/2026
Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions, and Electronic Submission Using FDA Form 3503	0910–0016	10/31/2026
Infant Formula Requirements	0910–0256	10/31/2026
Biologics License Applications; Procedures & Requirements	0910–0338	10/31/2026
Medical Devices; Reports of Corrections and Removals	0910–0359	10/31/2026
Customer/Partner Satisfaction Service Surveys	0910–0360	10/31/2026
Voluntary National Retail Food Regulatory Program Standards	0910–0621	10/31/2026
Expanded Access to Investigational Drugs for Treatment Use	0910–0814	10/31/2026
Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified and Thermally Processed Low-Acid Foods	0910–0037	11/30/2026
Color Additive Certification	0910–0216	11/30/2026
Reporting and Recordkeeping Requirements for Reportable Food	0910–0643	11/30/2026
Prescription Drug Advertisements; Presentation of Advertisements in Television and Radio	0910–0686	11/30/2026
Submission to CDRH Allegations of Regulatory Misconduct Associated with Medical Devices	0910–0769	11/30/2026
Importation of Prescription Drugs	0910–0888	11/30/2026

Dated: December 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Father Generic Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement 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 collection for public comment, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

DATES: Comments on the ICR must be received on or before February 20, 2024.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 264–0041 and PRA@HHS.GOV.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to

Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, PRA@HHS.GOV or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Improving Customer Experience (OMB Circular A–11, Section 280).

Type of Collection: Father Generic ICR.

OMB No.: 0990–XXXX, Office within Office of the Secretary, Assistant Secretary Administration.

Abstract: The Department of Health and Human Services, Office of the Secretary, Assistant Secretary Administration is requesting approval by OMB on a new Father Generic Information Collection Request. OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To

enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.*, in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. HHS will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on [performance.gov](https://www.performance.gov) to help build transparency and accountability of Federal programs to the customers they serve.

Implementation).