

OMB Control No. 0910-0032

New Animal Drug Applications; Abbreviated New Animal Drug Applications (21 CFR 514 and 558, and Section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc)); and Veterinary Master Files

**REQUEST FOR NON-SUBSTANTIVE/NON-MATERIAL CHANGE:**

The information collection supports implementation of section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b), which governs new animal drugs. Agency regulations in 21 CFR part 514 (21 CFR 514) and associated regulations in 21 CFR part 558, establish format and content requirements with regard to new animal drug application (NADA) submissions, as well as provide for pre-application submissions, amended applications, and application supplements. This information collection also supports implementation of section 571 of the FD&C Act regarding application for conditional approval of new animal drug (CNADA) submissions. As set forth in the FD&C Act and applicable regulations, requisite elements include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. Applications must be prepared as appropriate to support the particular submission. Respondents to the information collection are persons developing, manufacturing, and/or researching new animal drugs.

For the efficiency of agency operations, we are requesting to include burden attributable to related information collection activity for Abbreviated New Animal Drug Applications (ANDAs), currently included in OMB control no. 0910-0669. Information collection applicable to the submission of ANDAs is also governed by section 512 of the FD&C Act. Information required to be submitted as part of an ANADA is described in section 512(n)(1) of the FD&C Act, and establishes that an ANADA is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved new animal drug. Applicants are permitted to submit a complete ANADA or to submit information in support of an ANADA for phased review. Applicants may electronically submit Form FDA 356v with a complete ANADA or a phased review submission to ensure efficient and accurate processing of information.

While FDA extended the instant information collection earlier this year, extenuating circumstances have prevented us from issuing our requisite 30-day notice for activities covered by OMB control no. 0910-0669. Our 60-day published June 16, 2025 (90 FR 25319) announcing we intend no changes to the program. No public comments were received; however, the information collection expired November 30, 2025. Upon further evaluation, we believe the related collection activities may be included in one approval package. Because of the import we place on the underlying statutory requirements the regulations support, we are submitting this request to offset the expired approval period to the best of our ability.

To reflect the modification, we have added the following elements:

- *Abbreviated New Animal Drug Application Submissions.*
- *Biowaiver requests.*

To reflect an increase in submissions since last OMB review and approval under OMB control no. 0910-0669, we increased the approved estimate by 55 responses and 511 hours, and have included this in our current request.

**Form FDA 356v**, approved for use in OMB control number 0910-0032, is also used for ANDAs, and is available for download from our website at <https://www.fda.gov/about-fda/reports-manuals-forms/forms>. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

The information collection also includes applicant requests to waive the requirement to establish bioequivalence through in vivo studies (biowaiver requests) for soluble powder oral dosage form products or certain Type A medicated articles based upon either of two methods. We use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request. Therefore, the information collection references the guidance document GFI #171 “*Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to Be Soluble in Aqueous Media*” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-171-demonstrating-bioequivalence-soluble-powder-oral-dosage-form-products-and-type-medicated>) (June 2023), which discusses statutory bioequivalence requirements as well as qualifications for requesting a waiver from the requirements. The guidance document was developed consistent with the agency’s Good Guidance Practice regulations in 21 CFR 10.115, which provide for comment at any time.

**Submitted: December 2025**