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Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs with a New World Screwworm-Related Indication

Guidance for Industry

This guidance is for immediate implementation.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Comments may be submitted at any time for Agency consideration. Submit electronic comments to *https://www.regulations.gov*. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2025-D-4500, as listed in the notice of availability that publishes in the *Federal Register*.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740 and may be viewed on the Internet at https://www.fda.gov/animal-veterinary, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
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Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance via the contact information on the title page.

I. Introduction

This guidance is intended for sponsors seeking to combine fully approved and conditionally approved indications on a single new animal drug product label and labeling (dual labeling). The term "full approval" or "fully approved" is used herein when referring to an approval of a New Animal Drug Application (NADA) submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The term "conditional approval" or "conditionally approved" is used when referring to approval of a Conditional NADA (CNADA) under section 571 of the FD&C Act.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended but not required.

II. Background

In 2018, Congress amended the FD&C Act to eliminate language that had previously prohibited dual labeling of new animal drug products[1] and to replace it, in section 571(f)(2) of the FD&C Act, with language that permits the agency to "through regulation or guidance, determine under what conditions an intended use that is the subject of a conditional approval…may be included in the same product label with any intended use approved under section" 512 of the FD&C Act, i.e. a full approval. While section 571(f)(2) refers to inclusion of both claims on the "label" of the product, § 304(d)(3)(ii) of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018[2] refers to this practice as "dual labeling." The term "labeling" is broader than the term "label" and, includes "other written, printed, or graphic matter" either on the product or

[1] Section 571(f)(2) of the FD&C Act previously stated that "[a]n intended use that is the subject of a conditional approval under this section shall not be included in the same product label with any intended use approved under section 512."
[2] Public Law 115-234.

accompanying it.[3] Given the use of the term "labeling" in the latter statute, and because it would create confusion to label a product differently on the label and on other printed matter accompanying the product, we interpret section 571(f)(2) to allow dual claims on product labeling.

While FDA intends to issue guidance in the future addressing more broadly the conditions under which it would consider dual labeling to be permissible, we are issuing this guidance concerning products with indications for New World screwworm (*Cochliomyia hominivorax)* at this time to act quickly and efficiently to address the imminent health threat of New World screwworm.[4]

III. Dual Labeling Policy

FDA has determined that the labeling for a new animal drug product may include a fully approved intended use(s) and a conditionally approved intended use where the use to be added to the existing labeling is intended to treat or prevent New World screwworm myiasis.

IV. Adverse Drug Experience Reporting

A. Adverse Drug Experience (ADE) Report

ADE reports should be submitted electronically through the FDA's established electronic reporting systems.

- **NADA-Related ADEs**: Adverse drug experiences occurring in animals treated for the fully approved indication must be reported under existing post-approval requirements per 21 CFR 514.80

- **CNADA-Related ADEs**: ADEs in animals treated for the conditionally approved indication should be reported in the timeframes and manner specified in the conditional approval letter.

- **ADEs with Uncertain Attribution**: Where possible, sponsors should ascertain whether the treatment indication was related to conditional approval or full approval and put the treatment indication in the narrative description of the adverse event. If, after reasonable attempts are made to obtain this information, the indication cannot be ascertained, the sponsor should report adverse drug experiences to both NADA and CNADA applications and specify the indication could not be identified.

B. Product/Manufacturing Defect Reports

Sponsors should submit all product or manufacturing defect reports, including 3-day Field Alert Reports (FARs), under the NADA only (21 CFR 514.80(b)(1)).

[3] Section 201(m) of the FD&C Act, 21 U.S.C.§ 321(m)
[4] See 90 Fed. Reg. 40609, Aug. 18, 2025.

C. Periodic Drug Experience Reports (PDERs)

Sponsors should submit separate PDERs for each indication, clearly labeled with the corresponding approval number or conditional approval number through FDA's established reporting systems (21 CFR 514.80(b)(4)).

- **NADA PDER**: Sponsors should follow standard semiannual/annual reporting requirements for the fully approved indication.

- **CNADA PDER**: Sponsors should submit semiannual reports (6-month periodic drug experience reports) for the conditionally approved use during each year of the conditional approval.