

New World Screwworm: Frequently Asked Questions on Animal Drugs for Veterinarians

Q. What drugs have a label indication to treat and/or prevent NWS myiasis in animals?

A. On [New World Screwworm: Information for Veterinarians](#), FDA provides information to support veterinarians with the identification of drugs for NWS myiasis.

FDA has conditionally approved (CA) or issued Emergency Use Authorizations (EUA) for several drugs to treat or prevent NWS myiasis. These drugs can be used legally for NWS myiasis when used according to label directions. For these drugs, FDA has reviewed data regarding animal safety, effectiveness, and, if applicable, human food safety. To date, there are no drugs with a full FDA approval for NWS myiasis.

Q. What is the difference between an FDA approval, conditional approval and Emergency Use Authorization?

A. Approvals, conditional approvals, and Emergency Use Authorizations (EUA) are pathways and mechanisms by which FDA may approve or authorize an animal drug to be legally marketed in the U.S. The appropriate regulatory process for each drug depends on factors such as current U.S. approval status, which animal species the drug is indicated for, and data and information submitted for FDA review by a sponsor.

Comparison of FDA Approval, Conditional Approval, and Emergency Use Authorization for Animal Drugs for New World Screwworm (NWS)		
*Full Approval	**Conditional Approval (CA)	***Emergency Use Authorization (EUA)
Animal drug has completed the New Animal Drug Application (NADA) process or Abbreviated New Animal Drug Application (ANADA) process for generics and met all requirements for approval. Currently no animal drugs have full approval for NWS	Animal drug has met the standards for a full approval except substantial evidence of effectiveness. Animal drugs for NWS may be eligible for conditional approval because the drug prevents and/or treats a serious or life-threatening disease in animals, addresses an unmet animal health need, and demonstrating effectiveness would require complex or particularly difficult studies	Requires HHS Secretary determination and declaration (issued August 18, 2025, for NWS myiasis). An unapproved animal drug or unapproved use of an approved animal drug may be authorized for emergency use if statutory criteria are met, including that there are no adequate, approved and available alternatives to the authorized use

Regulatory Status		
Can be prescription (Rx), Veterinary Feed Directive (VFD), or over the counter (OTC) depending on FDA risk assessment		Can be Rx, VFD, OTC depending on FDA risk assessment. Additionally, FDA can set more specific limitations on who can distribute or administer the product, as appropriate
Duration of Approval/Authorization		
Approval without time limitation	Temporary approval status. Up to 5 years to obtain full approval	An EUA will remain in effect for the duration of the NWS declaration, unless the EUA is revoked sooner
Effectiveness		
Requires substantial evidence of effectiveness, which provides a high level of confidence that the drug produces the effect it claims	Requires a reasonable expectation of effectiveness. Has not yet proven that it meets the “substantial evidence” standard of effectiveness for full approval. Sponsor has up to 5 years to generate additional data needed to obtain full approval	Based on the totality of available scientific evidence, it is reasonable to believe that the drug may be effective in treating and/or preventing NWS
Target Animal Safety		
The drug sponsor must show that the drug is safe to the target animal species when it is used according to the label		Based on the totality of available scientific evidence, it is reasonable to believe that the known/potential benefits outweigh the known/potential risk when used under the conditions of authorization
Human Food Safety		
For non- food producing animals (such as cats and dogs), FDA does not require or review food safety data for full approvals, condition approvals, or EUAs.		
For food-producing animals (such as cattle and swine), FDA reviews food safety data for full approvals, conditional approvals, and EUAs and sets risk-based drug withdrawal times as necessary to ensure products from treated food animals (such as milk, eggs, and meat) are safe for human consumption.		
Extralabel Use for NWS		
Veterinarians may prescribe or use FDA-	Cannot be used in an extralabel manner unless the product also has	Cannot be used in an extralabel manner unless the product also has

approved products for NWS myiasis indications that are not on the product label, when done in accordance with the existing regulations	full FDA approval for non-NWS myiasis indications, and the extralabel use for NWS is in accordance with the existing regulations	full FDA approval for non-NWS myiasis indications, and the extralabel use for NWS is in accordance with the existing regulations
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*[From an Idea to the Marketplace: The Journey of an Animal Drug through the Approval Process | FDA](#)

**[Conditional Approval Explained: A Resource for Veterinarians | FDA](#)

***[Emergency Use Authorization | FDA](#)

Q. What extralabel uses of drugs to treat and/or prevent NWS myiasis are legally permissible?

A. Under the [Animal Medicinal Drug Use Clarification Act of 1994 \(AMDUCA\)](#) provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act, veterinarians may prescribe or use products with a full FDA approval for NWS myiasis indications that are not on the product label (extralabel use), when done in accordance with the existing regulations ([21 CFR Part 530](#)), with a valid veterinary/client/patient relationship.

The law does **not permit the extralabel use of conditionally approved or emergency-use authorized products** for NWS myiasis indications.

Some animal drugs have full FDA approval for non-NWS indications **and** conditional approval or an EUA for NWS. These animal drugs **can** be used in an extralabel manner because they have a full approval, even though conditionally approved or emergency use authorized drugs typically cannot be used in this way.

FDA encourages veterinarians to review existing regulations regarding the extra-label use of animal drugs. It is particularly important for food animal veterinarians to be aware of the additional requirements for extra-label use in food-producing animals including rules against the extra-label use of drugs administered as medicated feed. A helpful reference tool is: [The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians](#).

Q. How can veterinarians find more information about an animal drug for NWS that has been granted an Emergency Use Authorization (EUA)?

A. Veterinarians can find comprehensive information about EUA products through three primary sources: the Fact Sheet, the Letter of Authorization (LOA), and Freedom of Information (FOI) Summaries.

- **Fact Sheet:** This document provides essential information on conditions for use, data evaluated to support the EUA, and other product-specific guidance for veterinarians.

Similar to labeling for approved products but streamlined for emergency use, Fact Sheets include product descriptions, dosage and administration instructions, storage requirements, contact information, adverse reaction reporting procedures, and warnings. These documents remain in effect for the duration of the product's authorization. The Fact Sheet may physically accompany the product and/or be available electronically via QR code or website link. Because Fact Sheets may be updated with new information, veterinarians should review them regularly.

- **Letter of Authorization (LOA):** This document sets forth the legal terms and conditions of the authorization issued by FDA. It states the agency's conclusions about the product meeting statutory criteria, the authorized scope and limitations on the product's use, and conditions of the authorization that apply to those distributing, prescribing, or using drugs under an EUA (including veterinarians). For example, the LOA may require recordkeeping or adverse event reporting.
- **Freedom of Information (FOI) Summaries:** These summaries describe the safety and effectiveness information supporting approval of a New Animal Drug Application (NADA), Abbreviated New Animal Drug Application (ANADA), or Conditional New Animal Drug Application (CNADA) or to support authorization of an Emergency Use Authorization and FDA's conclusions after reviewing that information. For food-producing species, FOI Summaries also include human food safety study summaries.

EUAs for NWS are listed on the "New World Screwworm: Information for Veterinarians" page: <https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians> and include links to Fact Sheets, LOAs and FOI Summaries.

Q. What responsibilities do veterinarians have for informing clients regarding an EUA animal drug prior to use in their animal?

A. Veterinarians and veterinary facilities are responsible for ensuring that clients understand that the animal drug is authorized for emergency use (EUA), but not FDA-approved, for the treatment or prevention of NWS myiasis. The letter of authorization for prescription EUA products ordinarily state that the sponsor will ensure that the Fact Sheets are made available to veterinarians. The Fact Sheet may physically accompany the product and/or be available electronically via QR code or website link.

Veterinarians are responsible for informing clients of the potential risks and benefits of the drug, as well as any available alternatives. In addition, when an EUA drug is administered to food-producing animals, veterinarians must ensure that clients are aware of any applicable withdrawal times specified under the EUA.

Q. What are the record keeping requirements for veterinarians using or dispensing products for conditions identified as part of the EUA?

A. FDA's Letter of Authorization (LOA) for each animal drug contain the specific recordkeeping requirements. In general, veterinarian facilities (including veterinary hospitals, veterinary clinics,

and other establishments providing veterinary care) need to maintain detailed records when using or dispensing products under EUA conditions to ensure proper traceability and adverse event reporting capabilities. For both prescription and over-the-counter products prescribed or dispensed by veterinarians, patient records need to clearly identify when the product is used for EUA-specified conditions. This documentation allows adverse events to be traced back to the specific EUA use versus non-EUA applications.

When an LOA contains recordkeeping requirements for veterinarians, records generally refer to health records that include:

- Client name, patient name, patient age, disease manifestation
- Product information (number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs coadministered)
- Indication for use (specifically noting EUA conditions)

For most up to date version of this document, please visit: [New World Screwworm: Information for Veterinarians | FDA](#)