Date of Authorization: February 5, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006689

Ivomec®

(ivermectin)

Injectable solution

Cattle

Scope of Authorization: Prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal.

Sponsored by:

Boehringer Ingelheim Animal Health USA, Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006689

B. Sponsor

Boehringer Ingelheim Animal Health USA, Inc.
3239 Satellite Blvd.
Duluth, GA 30096

Drug Labeler Code: 000010

C. Proprietary Name

Ivomec®

D. Drug Product Established Name

ivermectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg ivermectin/mL (1%)

H. How Supplied

50 mL rubber-capped bottle, and 200 mL, 500 mL, and 1000 mL soft collapsible packs for use with an automatic syringe

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

200 mcg/kg body weight

K. Route of Administration

Subcutaneous

L. Species/Classes

Cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal

M. Food and Drug Administration (FDA) Approved Indications

Ivomec® (ivermectin) injection (NADA 128-409) is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice, and mange mites in cattle[1]:
Gastrointestinal Roundworms (adults and fourth-stage larvae): *Ostertagia ostertagi* (including inhibited *O. ostertagi*), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Bunostomum phlebotomum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only)
Lungworms (adults and fourth-stage larvae): *Dictyocaulus viviparus*
Cattle Grubs (parasitic stages): *Hypoderma bovis*, *H. lineatum*
Sucking Lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*
Mites (scabies): *Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*
Persistent Activity
Ivomec® (ivermectin) injection has been proved to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostrongylus axei* and *Cooperia punctata* for 21 days after treatment; *Haemonchus placei* and *Cooperia oncophora* for 14 days after treatment.

N. Emergency Authorized Use

Prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal.

O. Limitations of Authorized Use

Ivomec® (ivermectin) injection is not authorized for use in female dairy cattle of breeding age or in calves to be processed for veal.

Ivomec® (ivermectin) injection is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Ivomec® (ivermectin) injection under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

II. EFFECTIVENESS

A. Dosage Characterization

This Emergency Use Authorization does not change the previously approved 200 mcg/kg bodyweight dose, given subcutaneously. The FOI Summary for the original approval of NADA 128-409, dated February 13, 1984, contains dosage characterization information for cattle.

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[1] This product is also currently approved for various indications for swine, reindeer, and American bison.

B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that Ivomec® (ivermectin) injection may be effective for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle based on summaries of dose confirmation studies and published scientific literature.

1. Dose Confirmation Studies

Four dose confirmation studies conducted in Brazil and Argentina in 1991 and 1992 evaluated the effectiveness of Ivomec® injection for the prevention of infestations caused by NWS larvae (myiasis) in beef calves. All four studies included a group treated subcutaneously with a single dose of 200 mcg/kg body weight (BW) Ivomec® injection, and an untreated control group. Calves in the Ivomec® injection group were treated within 24 hours of birth or immediately following castration, and all study animals were housed on pastures (with their dams, if applicable), and exposed to natural infestations of NWS. NWS myiasis was observed in untreated control animals within the first week of birth or castration in all studies and no animals treated with Ivomec® injection had myiasis that required a rescue treatment. Additional details about the design and results of these studies are summarized in Table II.1 below.

Table II.1. Natural infestation Dose Confirmation Studies

Study Number	**13014**	**13015**	**13632**	**13940**
Study Date	1991	1991	1992	1992
Study Location	Argentina	Argentina	Brazil	Argentina
Study Animals	2-month-old male Brahman cross	Newborn (hours to one day old) male and female Brahman cross	4 to 6-month-old male Hereford or Hereford cross	2-month-old male Brahman cross
Animals/Group	10	10	10	10
Day of Treatment	Day 0	Day 0	Day 0	Day 0
Incidence of Myiasis in Control Group	3/10 with scrotal myiasis on Days 3 and 4	8/9 with naval myiasis on Days 3 and 4	9/10 with scrotal myiasis*	4/10§ with scrotal myiasis on Days 5 to 7
Incidence of Myiasis in Ivomec® Injection Group	No myiasis observed	No myiasis observed	No rescue treatment required¥	No myiasis observed

* All lesions (10/10) infested but 9/10 required rescue treatment by Days 6 to 8
¥ Eggs and/or larvae were detected in 8/10 animals treated with Ivomec® injection, but none required separate curative topical rescue treatment
§ One additional control animal had myiasis at a dehorning site

2. Published literature

   Studies conducted in Argentina and Brazil and published in the scientific literature between 1993 and 2022, evaluated the effectiveness of a single subcutaneous dose of 200 mcg ivermectin/kg BW for the prevention of natural and induced infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle.

   a. Anziani, O. S., & Loreficce, C. (1993). Prevention of cutaneous myiasis caused by screw worm larvae (*Cochliomyia hominivorax*) using ivermectin. *Zentralbl Veterinarmed B*, *40*(4), 287-290.

      Four studies were conducted in Argentina in March of 1991 and 1992. In the first study, 24 steers were artificially wounded, in the second and third studies 36 and 20 bull calves were castrated, and in the fourth study, 30 newborn calves were enrolled within 24 hours of birth. On the same day, half of the animals in each study were treated with Ivomec® (ivermectin) injection and the other half of the animals were used as untreated controls. Treatment with Ivomec® (ivermectin) injection prevented natural infestations of NWS myiasis in all treated animals. Within the untreated controls, 3 of 12 (25%) artificially wounded, 8 of 18 (44%) castrated, 5 of 10 (50%) castrated, and 8 of 15 (53%) newborn animals developed active myiasis in the first 7 to 9 days in studies 1 to 4, respectively.

   b. Benitez Usher, C., et. al., (1997). Prophylactic use of ivermectin against cattle myiasis caused by *Cochliomyia hominivorax* (Coquerel, 1858). *Vet Parasitol*, *72*(2), 215-220.

      Eight studies were conducted in Argentina and Brazil in calves maintained on pasture and naturally exposed to *Cochliomyia hominivorax*. In two studies, 26 calves were treated with Ivomec® (ivermectin) injection within 24 hours of birth, and another 25 calves remained untreated. In the other six studies, 99 calves were treated with Ivomec® (ivermectin) injection immediately after castration, and another 60 calves were left untreated. Two of 99 with Ivomec® (ivermectin) injection-treated calves developed naval myiasis, compared to 24 of 25 control calves; and 2 of 79 Ivomec® injection-treated calves developed scrotal myiasis, compared to 36 of 60 control calves.

   c. de Aquino, L. M., et. al., (2022). Number of rainy days in a week influencing screwworm navel myiasis in beef calves and efficacies of injectable and topical antiparasitics. *Res Vet Sci*, *152*, 698-706.

      A study was conducted in Brazil during the rainy season to evaluate the effectiveness of a variety of topical and injectable products, including 15 calves treated with ivermectin injection on the day of birth for the prevention of naval myiasis. Effectiveness (%) was calculated as [(number of control calves with active myiasis – number of treated calves with active myiasis)/ (number of control calves with active myiasis)] x 100. The effectiveness of ivermectin injection was 28.5% at 3 days and 13.5% at 7 days post-treatment when compared to the saline-control group (15 calves).

Collectively, although the effectiveness results were variable between studies, the information from dose confirmation study summaries and published literature support that it is reasonable to believe that Ivomec® (ivermectin) injection may be effective for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, or at the time of castration or the appearance of a wound in cattle.

III. TARGET ANIMAL SAFETY

FDA did not require additional target animal safety studies for this authorization because the species, class, dose, and route of administration are the same for the approved use and the authorized use. FDA's review and determination of target animal safety for the approved use is adequate to support this authorization. The FOI Summary for the original approval of NADA 128-409 dated February 13, 1984, contains a summary of target animal safety studies for cattle.

IV. HUMAN FOOD SAFETY

FDA did not require additional human food safety studies for this authorization because the species, class, dose, and route of administration are the same for the approved use and the authorized use. FDA's review and determination of human food safety for the approved use is adequate to support this authorization. The FOI Summaries for the original and supplemental approvals of NADA 128-409 dated February 13, 1984, September 13, 1995, and April 1, 1999, and the supplemental approval of NADA 140-833 dated August 13, 2014, contain the human food safety information for ivermectin in cattle.

The withdrawal period for this Emergency Use Authorization of Ivomec® (ivermectin) injection is 35 days, as established under NADA 128-409. Because a milk discard time has not been established for this drug product, do not use in female cattle producing milk for human consumption. A withdrawal period has not been established for this drug product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

V. USER SAFETY

The authorized Fact Sheet contains the following information, consistent with the approved labeling in NADA 128-409, regarding safety to humans handling, administering, or exposed to Ivomec®:

Not for use in humans. Keep out of reach of children.

VI. AGENCY CONCLUSIONS

Based on the scientific evidence available to FDA, including summaries of dose confirmation studies and published scientific literature, it is reasonable to believe that Ivomec® (ivermectin) injection, when used as authorized, may be effective for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for

human consumption and calves that will be processed for veal. The known and potential benefits of Ivomec® (ivermectin) injection when used as authorized outweigh the known and potential risks because NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by NWS larvae (myiasis). Therefore, the benefit of potentially preventing adverse health consequences from NWS outweighs the potential risk associated with the use of the drug. Finally, there is no adequate, approved, and available alternative to the product for prevention of New World screwworm (myiasis) in certain cattle for the authorized indications because the conditionally approved products are not available in sufficient quantities to meet the demands of a widescale incursion of NWS into the United States. Additionally, it was concluded that residues in food products derived from cattle treated with Ivomec® will not represent a public health concern when the product is used as authorized.

This is the first EUA of any over the counter drug for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) for cattle in the United States.

Other therapeutics are conditionally approved for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle. However, these products are not available alternatives. The emergency use authorization for this product will help meet needs in circumstances where the existing conditionally approved products would not be available in sufficient quantities to meet demand. In addition, one conditionally approved product is not an adequate alternative because it requires a prescription, potentially delaying administration. There is a significant benefit to expedient administration of a preventative product, particularly if animals nearby are infected. Because cattle are at particular risk, a sufficient supply of products is needed to adequately address an NWS incursion. Thus, FDA concluded that this additional OTC injectable macrocyclic lactone product indicated for prevention of NWS in cattle is needed to meet the demands of a widescale incursion of NWS into the United States.

For additional information on all products authorized or conditionally approved for use to treat or prevent New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under section 564(c) of the FD&C Act, or other circumstances make such revision or revocation of the authorization appropriate to protect the public health or safety (section 564(g)(2) of the FD&C Act).

B. Marketing Status

This product is authorized to be marketed OTC because the authorized labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.