Date of Authorization: August 27, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006729

Bimectin®

(ivermectin)

Injectable solution

Cattle

Scope of Authorization: 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.

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

EUA 006729

B. Sponsor

Bimeda Animal Health Ltd.
1B The Herbert Building, The Park
Carrickmines, Dublin 18
Ireland

Drug Labeler Code: 061133

U.S. Agent Name and Address:

Stephanie Batliner
Bimeda Inc.
475 N. Martingale Rd, Suite 1200
Schaumburg, IL 60173

C. Proprietary Name

Bimectin®[1]

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, 250 mL, 500 mL, and 1000 mL plastic bottles suitable for use with automatic syringe equipment

[1] Bimectin® (ivermectin) injection is also distributed by Aspen Veterinary Resources®, LTD; Durvet, Inc.; and MWI under the proprietary names IVERMAX®; Ivermectin; and Vetrimec™ 1%, respectively. All references to Bimectin® in this FOI Summary include each of the drugs sold under the aforementioned proprietary names.

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

200 mcg/kg body weight

K. Route of Administration

Subcutaneous injection

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

Bimectin® (ivermectin) injection (ANADA 200-447) 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[2]:
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
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

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.

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

O. Limitations of Authorized Use

Bimectin® (ivermectin) injection is not authorized for use in female dairy cattle producing milk for human consumption and calves that will be processed for veal.

Bimectin® (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 Bimectin® (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 the authorization is revoked sooner.

II. BIOEQUIVALENCE

FDA did not require additional bioequivalence information for this authorization. Bimectin® (ivermectin) injection contains the same active ingredient in the same concentration and dosage form as the reference listed new animal drug (RLNAD), and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is ivomec® (ivermectin) injection, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 128-409, and was approved for use in cattle on February 13, 1984. The FOI Summary for the original approval of ANADA 200-447, dated July 5, 2011, contains a summary of the basis for granting a biowaiver for Bimectin® (ivermectin) injection for use in cattle.

III. EFFECTIVENESS

A. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor provided information to support that it is reasonable to believe that Bimectin® may be effective for the prevention of infestations caused by New World screwworm (NWS, *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 dose confirmation studies and published scientific literature performed with the RLNAD, ivomec® (ivermectin) injection. The evidence supporting effectiveness is based on bioequivalence to ivomec® (ivermectin) injection and the summarized studies performed with ivermectin injection.

1. Dose Confirmation Studies

Four dose confirmation studies conducted in Brazil and Argentina in 1991 and 1992 evaluated the effectiveness of ivermectin 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) ivermectin injection, and an untreated control group. Calves in the ivermectin 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 ivermectin injection had

myiasis that required a rescue treatment. See the FOI Summary for EUA 006689, for more details on the dose confirmation studies.

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. *Zentralblatt fur Veterinarmedizin. Reihe B. Journal of Veterinary Medicine. Series 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 ivermectin injection and the other half of the animals were used as untreated controls. Treatment with 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). *Veterinary Parasitology*, *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 ivermectin injection within 24 hours of birth, and another 25 calves remained untreated. In the other six studies, 99 calves were treated with ivermectin injection immediately after castration, and another 60 calves were left untreated. Two of 99 with ivermectin injection-treated calves developed navel myiasis, compared to 24 of 25 control calves; and 2 of 79 ivermectin 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. *Research in Veterinary Science*, *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 navel 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 supports that it is reasonable to believe that Bimectin® (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.

IV. TARGET ANIMAL SAFETY

FDA did not require 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. The FOI Summary for the original approval of ANADA 200-447 dated July 5, 2011, contains a summary of the basis for concluding bioequivalence to the RLNAD, which was shown to be safe and effective, as referenced in the original approval (ANADA 200-447).

V. 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 Summary for the original approval of ANADA 200-447 dated July 5, 2011, contains the human food safety information for Bimectin® (ivermectin) injection in cattle.

The withdrawal period for this Emergency Use Authorization of Bimectin® (ivermectin) injection is 35 days, as established under ANADA 200-447. 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.

VI. USER SAFETY

The authorized Fact Sheet contains the following information, consistent with the approved labeling in ANADA 200-447, regarding safety to humans handling, administering, or exposed to Bimectin®:

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

VII. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including Bimectin®'s established bioequivalence to the RLNAD and summaries of data from studies performed on ivermectin injection, it is reasonable to believe that Bimectin®, 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, and that the known and potential benefits of Bimectin® outweigh the known and potential risks, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae. Additionally, data demonstrate that residues in food products derived from cattle treated with Bimectin® will not represent a public health concern when the product is used as authorized.

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 considered adequate and available alternatives for the purpose of this analysis. The existing conditionally approved injectable product is not an available alternative because there are insufficient quantities to meet the demands of a widescale incursion. The emergency use authorization for this product will help meet needs in circumstances where this existing conditionally approved product would not be available in sufficient quantities to meet demand. The conditionally approved topical product is not an adequate alternative because it is a different pharmacological class with a different route of administration, and its label restricts use to cattle two months of age and older. Furthermore, because this topical product requires a prescription, it is not a readily available alternative, as the requirement for veterinary intervention could potentially delay 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 potential widescale incursion of NWS into the United States.

For additional information on all products authorized or conditionally approved for use to treat and/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 revocation or revision 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.