Date of Approval: September 30, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

APPLICATION FOR CONDITIONAL APPROVAL

Application number 141-616

DECTOMAX®-CA1

(doramectin injection)

Injectable solution

Cattle

DECTOMAX®-CA1 is indicated for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle.

Sponsored by:

Zoetis Inc.

Executive Summary

DECTOMAX®-CA1 (doramectin injection) is conditionally approved for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle.

The Food and Drug Administration (FDA) determined that DECTOMAX®-CA1 is eligible for conditional approval for the labeled use under section 571(a)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because the drug prevents and/or treats a serious or life-threatening disease in cattle, addresses an unmet animal health need, and demonstrating effectiveness would require complex or particularly difficult studies. An animal drug that meets these criteria is eligible for conditional approval.

A conditionally approved animal drug has been shown to be safe and has a reasonable expectation of effectiveness. During the conditional approval period, the sponsor can legally market the drug for the labeled use while collecting the remaining effectiveness data. The conditional approval is valid for one year. The sponsor can ask FDA to renew the conditional approval annually for up to four more years, for a total of five years of conditional approval. To receive a renewal from FDA, the sponsor must show active progress toward proving substantial evidence of effectiveness for full approval.

DECTOMAX® is already fully approved under New Animal Drug Application (NADA) 141-061 for treatment and control of certain nematode and arthropod parasites in cattle and swine.

DECTOMAX® and DECTOMAX®-CA1 contain the same active ingredient, doramectin, at the same dose. DECTOMAX®-CA1 is available in 250 mL and 500 mL bottles. Its label will contain both DECTOMAX® and DECTOMAX®-CA1 indications while each drug has a unique application number.

For this conditional approval, the sponsor provided the following study summaries to support reasonable expectation of effectiveness: five field studies utilizing natural *C. hominivorax* infestations; four dose confirmation studies utilizing induced *C. hominivorax* infestations; and nine comparative studies utilizing a mix of natural and induced infestations. All studies took place in South America between 1990 and 1999. For more information on these study summaries, see the Effectiveness section below. FDA concluded these study summaries were acceptable to support reasonable expectation of effectiveness for conditional approval.

FDA did not require new safety studies in cattle for this conditional approval. The dose of doramectin in DECTOMAX®-CA1 is identical to the dose in DECTOMAX®, which is fully approved under NADA 141-061. Therefore, the safety of the drug in cattle is supported by the target animal safety studies and field effectiveness studies conducted for the approval of NADA 141-061.

FDA did not require new human food safety information in cattle for this conditional approval. The FOI Summaries for the original approval of NADA 141-061 dated July 30, 1996, and the original approval of NADA 141-553 dated September 9, 2022, contain summaries of all studies and information used to assess human food safety for doramectin in cattle. The withdrawal period for cattle remains 35 days for

DECTOMAX®-CA1 as it is for DECTOMAX®. Residue warnings remain the same for DECTOMAX®-CA1 as for DECTOMAX®: Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Table of Contents

I. GENERAL INFORMATION

A. File Number

Application number 141-616

B. Sponsor

Zoetis Inc.
333 Portage St.
Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Name

DECTOMAX®-CA1

D. Drug Product Established Name

doramectin injection

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg/mL

H. How Supplied

250 mL and 500 mL multi-dose, rubber capped glass vials

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg) administered by subcutaneous or intramuscular injection in the neck region.

K. Route of Administration

Injection

L. Species/Class

Cattle

M. Indication

DECTOMAX®-CA1 is indicated for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle.

II. EFFECTIVENESS

Conditional Dose: The conditional dose for the indication "for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle" is 1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg) administered by subcutaneous or intramuscular injection in the neck region. The safety data and the data to demonstrate reasonable expectation of effectiveness provide support for this conditional dose.

A. Dosage Characterization

The dosage of doramectin injection that is effective against *C. hominivorax* has been approved in Mexico and Brazil and is the same as the dosage characterized for the original approval of NADA 141-061. The FOI Summary for the original approval of NADA 141-061 dated July 30, 1996, contains dosage characterization information for cattle.

B. Reasonable Expectation of Effectiveness

Reasonable expectation of effectiveness for DECTOMAX®-CA1 (doramectin injection) for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle is based on the results of 18 study summaries provided by the sponsor. These studies were conducted in various South American countries from 1990 to 1999 and included induced and natural infestations in a variety of cattle ages and breeds. Both male and female cattle were represented. Nine of these studies were dose confirmation and field studies, summarized in the table below.

Table II.1: Summary of Dose Confirmation and Field Studies

Study Number	Study/Infestation Type	Study Duration	Study Location	Animals/ Group	Percent Efficacy	Indication Supported
2039A-04-89-006	Dose confirmation/ induced	8 days	Brazil	6/group	100% after 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*
2039A-04-90-001	Dose confirmation/ induced	8 days	Brazil	6/group	100% after 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*

Study Number	Study/Infestation Type	Study Duration	Study Location	Animals/ Group	Percent Efficacy	Indication Supported
2039A-04-92-008	Dose confirmation/ induced	22 days	Brazil	4/group	100% after 24 hours	Prevention of infestations caused by larvae of *C. hominivorax*
2039A-04-92-005	Dose confirmation/ induced	36 days	Brazil	4/group	100% after 24 hours	Prevention of reinfestations caused by larvae of *C. hominivorax* up to 21 days.
2039A-04-91-029	Field study/natural	12 days	Brazil	20/group	100% within 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*
2039A-05-91-009	Field study/natural	12 days	Argentina	21/treated 20/control	100% within 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*
2039A-26-91-002	Field study/natural	12 days	Venezuela	28/group	100% within 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*
2039A-26-91-003	Field study/natural	12 days	Venezuela	25/group	100% within 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*
2039A-05-92-001	Field study/natural	12 days	Argentina	21/group	100% within 48 hours	Prevention of infestations caused by larvae of *C. hominivorax*

In nine other studies, doramectin injection was compared to another drug. Both induced and natural infestations were utilized across these studies, with varying cattle ages and breeds represented. These studies took place between 1991 and 1999 in various South American countries. Some of these comparative studies were multi-site field studies.

The induced infestation comparative studies demonstrated 100% efficacy of doramectin injection for treatment and prevention of myiasis over varying lengths of time. The multi-site natural infestation studies demonstrated efficacy ranging from 53% to 100% for the prevention of myiasis caused by the larvae of *C. hominivorax*

for varying lengths of time. Over 2,000 animals were treated with doramectin injection across these nine comparative studies.

Evaluated together, the 18 studies summarized above demonstrate reasonable expectation of effectiveness for DECTOMAX®-CA1, administered at the label dose of 1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg), for the prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle.

III. TARGET ANIMAL SAFETY

As the dosage of doramectin in DECTOMAX®-CA1 is identical to that of DECTOMAX® for cattle, approved under NADA 141-061, the target animal safety for DECTOMAX®-CA1 is supported by the target animal safety studies conducted for the approval of DECTOMAX®. The FOI Summary for the original approval of NADA 141-061 dated July 30, 1996, contains a summary of target animal safety studies for cattle.

IV. HUMAN FOOD SAFETY

A. Microbial Food Safety

The Center for Veterinary Medicine (CVM) did not require additional information for microbial food safety (antimicrobial resistance) for this conditional approval. The FOI Summary for the original approval of NADA 141-553 dated September 9, 2022, contains a summary of all information used to assess microbial food safety (antimicrobial resistance) risks.

B. Toxicology

Reassessment of the acceptable daily intake (ADI), Acute Reference Dose (ARfD), and safe concentrations was not needed for this conditional approval. The codified ADI for total residue of doramectin is 0.75 micrograms per kilogram of body weight per day (µg/kg bw/day), as listed under 21 CFR 556.222. The ARfD for total residue of doramectin is 66 µg/kg bw. The safe concentrations for total residue of doramectin in the edible tissues of cattle are 150 parts per billion (ppb) for muscle, 450 ppb for liver, 900 ppb for kidney, 900 ppb for fat, and 13.2 parts per million (ppm) for the injection site.

The FOI Summaries for the original approval of NADA 141-061 dated July 30, 1996, and the original approval of NADA 141-553 dated September 9, 2022, contain summaries of all toxicology studies and information for doramectin.

C. Residue Chemistry

CVM did not require residue chemistry studies for this conditional approval. The FOI Summary for the original approval of NADA 141-061 dated July 30, 1996, contains a summary of residue chemistry studies for cattle.

This conditional approval does not result in any changes to the previously established withdrawal period. The withdrawal period remains 35 days. Refer to the FOI Summary for the original approval of NADA 141-061 dated July 30, 1996.

D. Analytical Method for Residues

The FOI Summary for the original approval of NADA 141-061 dated July 30, 1996, contains the analytical method summaries for doramectin in cattle.

V. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to DECTOMAX®-CA1:

Not for human use. Keep out of reach of children. The safety data sheet (SDS) contains more detailed occupational safety information.

VI. AGENCY CONCLUSIONS

The data submitted in support of this application satisfy the requirements of section 571(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The data demonstrate that DECTOMAX®-CA1, when used according to the label, is safe and has a reasonable expectation of effectiveness for the conditions of use in the General Information Section above. Additionally, data demonstrate that residues in food products derived from species treated with DECTOMAX®-CA1 will not represent a public health concern when the product is used according to the label.

A. Conditional Approval Eligibility

In 2018, the legislation reauthorizing FDA's animal drug user fee program (Animal Drug User Fee Program, or ADUFA, IV) expanded the conditional approval pathway to allow certain additional new animal drugs that are not Minor Use/Minor Species (MUMS) drugs to be eligible for conditional approval. As provided in section 571(a)(1)(A)(ii) of the FD&C Act, as amended by ADUFA IV, to qualify for conditional approval, the non-MUMS new animal drug must meet the following two criteria:

1. The new animal drug is intended to treat a serious or life-threatening disease or condition OR addresses an unmet animal or human health need; AND

2. A demonstration of effectiveness would require a complex or particularly difficult study or studies.

DECTOMAX®-CA1 was determined to be eligible for conditional approval under these provisions because it prevents and treats a serious or life-threatening disease or condition, addresses an unmet animal health need, and the demonstration of effectiveness requires a complex or particularly difficult study or studies. The tissue damage caused by *Cochliomyia hominivorax* in cattle can be serious and is often deadly to the animal. Therefore, the conditionally approved use of DECTOMAX®-CA1 addresses a serious or life-threatening disease or condition. The prevention and treatment of infestations caused by larvae of *C. hominivorax* (myiasis) and prevention of reinfestation for 21 days is also an unmet animal health need because currently there is no approved animal drug in the United States for this use in cattle. Finally, demonstrating effectiveness would require a complex or particularly difficult

study, or studies, because *C. hominivorax* has been eradicated in the United States, making it impossible to conduct studies in the United States using naturally infested animals to provide substantial evidence of effectiveness. Additionally, there are significant animal welfare concerns when considering whether to conduct studies with this parasite. Therefore, the FDA determined that DECTOMAX®-CA1 met the eligibility criteria for conditional approval.

B. Marketing Status

DECTOMAX®-CA1 is conditionally approved for one year from the date of approval and is annually renewable for up to four additional one-year terms.

This product can be marketed over the counter (OTC) because the approved 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.

C. Exclusive Marketing Rights

DECTOMAX®-CA1, as approved in our approval letter, does not qualify for exclusive marketing rights under section 573(c) of the FD&C Act because it is not a designated new animal drug under section 573(a) of the FD&C Act.

D. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.