

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in August 2019.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-465

Trade Name: Integrity™ and Coban™
Ingredients: Avilamycin and monensin
Sponsor: Elanco US Inc.
Approval Date: August 27, 2019

This supplement provides for a change in the broiler chicken age restriction caution statement from 10 days to 18 days of age as follows: To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age.

NADA Number: 141-467

Trade Name: Integrity™ and Monteban™
Ingredients: Avilamycin and narasin
Sponsor: Elanco US Inc.
Approval Date: August 27, 2019

This supplement provides for a change in the broiler chicken age restriction caution statement from 10 days to 18 days of age as follows: To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age.

NADA Number: 141-495

Trade Name: Integrity™ and Bio-Cox®
Ingredients: Avilamycin and salinomycin sodium
Sponsor: Elanco US Inc.
Approval Date: August 27, 2019

This supplement provides for a change in the broiler chicken age restriction caution statement from 10 days to 18 days as follows: To assure reasonable antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age.

Post Approval Experience Labeling Changes

NADA Number: 110-047

The following statement was added to the Warnings section:

"Parasite resistance may develop to any dewormer. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring."

NADA Number: 116-044

The following statement was added to the Warnings section:

"Parasite resistance may develop to any dewormer. All dewormers require accurate dosing for best results. Following the use of any dewormer, effectiveness of treatment should be monitored. A decrease of effectiveness over time may indicate the development of resistance to the dewormer administered. The parasite management plan should be adjusted accordingly based on regular monitoring."

NADA Number: 121-042

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in August 2019.

The following statements were added to the labeling:

"Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance. Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method). A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring."

"Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance."

NADA Number: 129-831

The following statements were added to the labeling:

"Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance."

"Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance. Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method). A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring."

Sponsor Change

NADA Numbers: 140-872

Previous Sponsor:	Elanco US Inc.
New Sponsor:	Union Agener, Inc.
Drug Labeler Code:	86106

Withdrawal of Approval

NADA Number: 141-054

Sponsor:	Boehringer Ingelheim Animal Health USA Inc.
Trade Name:	IVOMEC® plus LINCOMIX®
Ingredients:	Ivermectin and lincomycin hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

NADA Number: 141-337

Sponsor:	Elanco US Inc.
Trade Name:	Recuvyra®
Ingredients:	Fentanyl

This product is withdrawn because the product is no longer manufactured or marketed.