Finding of No Significant Impact (FONSI)
in support of the supplemental approval of a new animal drug application (NADA)
for
Corid® 9.6% Oral Solution
in
calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age; not for use in veal calves
for
an aid in the prevention and treatment of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.[1]

Huvepharma EOOD
Peachtree City, GA

The Center for Veterinary Medicine (CVM) has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and, therefore, an environmental impact statement will not be prepared.

Huvepharma EOOD is requesting the supplemental approval of a new animal drug application (NADA) for the use of Corid® 9.6% Oral Solution (amprolium) in calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age, and not for use in veal calves, for an aid in the prevention and treatment of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.[1] Corid® 9.6% Oral Solution is administered in drinking water or as a drench for the treatment protocol at a dose of 10 mg amprolium/kg (10 mg per 2.2 lb body weight) for 5 days, or for the prevention protocol at a dose of 5 mg amprolium/kg (5 mg per 2.2 lb body weight) for 21 days. The sponsor also proposes to reduce the withdrawal time from one to zero days. The product will be dispensed over the counter.

In support of the application, Huvepharma EOOD has provided an environmental assessment (EA) titled, "ENVIRONMENTAL ASSESSMENT For Use of Corid® (Amprolium) Premix, Oral Solution, and Soluble Powder in Cattle for the Prevention and Treatment of Coccidiosis." A copy of the EA can be found on the Food and Drug Administration's (FDA's) CVM website titled "Animal Drugs @ FDA" under the Environmental Documents tab.[2] CVM provided guidance to and assisted Huvepharma EOOD by outlining the types of environmental information required for inclusion in the EA. CVM independently evaluated the EA to ensure the scope and content were adequate and to ensure that the information presented in the EA was accurate. CVM determined that the EA provides sufficient evidence to support a finding of no significant impact (FONSI).

The EA was prepared following CVM's Guidance for Industry (GFI) 166 [(VICH GL38) "Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's) - Phase II"] and includes a description of the product and its proposed use, exposure and effects assessments, and a risk characterization. For the exposure assessment, predicted

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[1] Incorrectly spelled as "*E. zurnii*" on the drug labelling.
[2] https://animaldrugsatfda.fda.gov/adafda/views/#/environmentalAssessments

environmental concentrations (PECs) in soil and surface water (PEC_{soil} and PEC_{water}) were calculated for cattle on pasture and intensively-reared cattle by assuming 100% of the dose was excreted into manure and applied to soil, without accounting for loss processes, such as metabolism or degradation in the environment, and are thus conservative. All PEC values in soil and surface water are summarized in Table 6-6 and Table 6-7 of the EA. The highest PEC_{soil} was 3,650 mg/kg dry weight soil for intensively-reared beef cattle. The highest PEC_{water} was 33.82 µg/L for growing beef cattle on pasture.

For the effects assessment, predicted no effect concentrations (PNECs) were derived for terrestrial organisms (nitrogen-transforming bacteria, plants, and earthworms) and aquatic organisms (algae, cyanobacteria, invertebrates, and fish) from toxicity studies conducted by Huvepharma EOOD. Plants were found to be the most sensitive terrestrial organisms (effects values for the Tier A and B plant toxicity studies are summarized in Tables 7-1 and 7-2 in the EA). The lowest no observed effect concentration (NOEC) from the Tier B plant toxicity study was 44.2 mg/kg dry weight for both cabbage and radish, which resulted in the PNEC value of 4.42 mg/kg dry weight when the NOEC was divided by an assessment factor (AF) of 10 as recommended in CVM's GFI 166. Algae was found to be the most sensitive aquatic organism in the toxicity studies (effects values for all aquatic organisms are summarized in Table 7-3 of the EA); however, invertebrates (*Daphnia magna*) and fish (*Danio rerio*) had the lowest PNEC values due to differences in the AFs used to derive the PNEC for each organism tested. The lowest median effects concentration (EC_{50}) was 41.265 mg/L for algae (*Pseudokirchneriella subcapitata*), which resulted in a PNEC of 412.6 µg/L (or 0.4126 mg/L) when the EC_{50} is divided by an AF of 100. Whereas, the lowest PNEC value was 88.4 µg/L for both invertebrates (*Daphnia magna*) and fish (*Danio rerio*) when their EC_{50} values (both > 88.4 mg/L) are divided by an AF of 1000 as recommended in CVM's GFI 166.

Using the results of the exposure and effects assessments, a risk characterization was performed that utilized a risk quotient (RQ) method (i.e., the ratio of the PEC to the PNEC). All RQs for aquatic organisms are below 1, indicating that there are no significant environmental impacts expected to aquatic organisms. The RQs for earthworms and all but two of the terrestrial plants are below 1. The RQs for French bean and radish were greater than 1 (i.e., 1.44) based on a Tier A terrestrial plant toxicity study, indicating a potential risk for terrestrial plants. Therefore, the risk characterization in the EA for plants proceeded to Tier B following CVM's GFI 166 in which the risk was further assessed using the toxicity data from the Tier B terrestrial plant toxicity study. When the Tier B PNEC values were compared to the highest PEC_{soil} value, the RQs from the Tier B risk characterization are all less than 1, indicating that there are no significant environmental impacts expected to terrestrial plants.

Based on the information in the EA, no significant environmental impacts are expected from the proposed use of Corid® 9.6% Oral Solution in calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age (and not for use in veal calves), as an aid in the prevention and treatment of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.[1]

{see appended electronic signature page}

Matthew Lucia, DVM
Director
Office of New Animal Product Evaluation
Center for Veterinary Medicine
U.S. Food and Drug Administration

Electronic Signature
Addendum for Submission ID

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Matthew Lucia (Office Director)	06/18/2026

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