FINDING OF NO SIGNIFICANT IMPACT

for

Establishment of an Import Tolerance for Permissible Monepantel Residues in Food Derived from Sheep that has been Imported into the United States for Human Consumption

Elanco Animal Health US, Inc.

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

Elanco Animal Health has submitted a request to establish an import tolerance for monepantel residues in food derived from sheep that has been imported into the US for human consumption. In support of the establishment of an import tolerance, Novartis Animal Health has prepared the attached environmental assessment (EA), dated December 16, 2015. The EA evaluated the potential effects of monepantel, and it's primary metabolite, monepantel sulfone, on the US environment arising through two potential points of introduction: 1) landfills that may hold seized materials containing residues of the drug in imported meat, and 2) wastewater treatment plant effluents that contain residues of the drug in human excreta due to consumption of the imported meat.

The potential environmental exposure in surface waters to monepantel and monepantel sulfone residues from wastewater discharges were determined to be very low due to several factors: 1) the use of monepantel in a species that is a minor part of the US consumer diet, 2) additional metabolism of drug residues in the human body, 3) the spatial and temporal variability of the distribution of human excreta containing drug residues, and 4) further removal of the drug and it's metabolites during the wastewater treatment. In addition, monepantel is not expected to migrate out of US landfills containing seized materials because landfills are highly regulated and are required to be lined. Therefore, leachates from landfills are highly controlled and not expected to enter the environment in significant amounts.

Based on the information provided in the EA as discussed above, no significant effects are expected to occur in the US due to very limited exposure to monepantel and monepantel sulfone.

An assessment of the exposure pathway and fate data leads to the conclusion that no significant environmental impacts are expected from the introduction of monepantel or monepantel sulfone residues into the US environment from wastewater or landfills. Thus, no further assessment of environmental impact is necessary.

The information available is adequate to conclude that establishing an import tolerance for monepantel in sheep is not expected to have a significant impact on the environment of the United States.

{see appended electronic signature page}

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