

FINDING OF NO SIGNIFICANT IMPACT (FONSI)

for

Establishment of an Import Tolerance for Permissible Benzocaine Residues in Food Derived from Atlantic Salmon and Rainbow Trout that has been Imported into the United States for Human Consumption

ACD Pharmaceuticals AS

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.

ACD Pharmaceuticals has submitted a request to establish an import tolerance for benzocaine residues in food derived from Atlantic salmon and rainbow trout that has been imported into the US for human consumption. In support of the establishment of an import tolerance, ACD Pharmaceuticals AS has prepared the attached environmental assessment (EA), dated May 11, 2017. The EA evaluated the potential effects of benzocaine on the US environment arising through two general types of exposure pathways: 1) pathways arising from the release of benzocaine residues, if present, from imported food derived from treated fish, and 2) pathways arising from use of the drug on fish in countries where it is legally authorized. With respect to the first exposure pathway, two potential points of introduction were evaluated: landfills that may hold seized materials (e.g., fish fillets) or waste from fish processing plants containing the drug, and wastewater treatment plant effluents and biosolids that contain residues of the drug from human excreta.

Information was incorporated and discussed as appropriate in the EA on benzocaine metabolism and residues in fish tissues, adsorption and mobility in soil and sediment, and degradation and persistence in the aquatic environment.

Benzocaine is not expected to migrate out of US landfills containing seized materials and waste from fish processing plants. Migration is precluded because landfills are highly regulated by local, state, and federal authorities to prevent environmental contamination, and most landfills are required to have caps and liners to prevent leaching of water and other fluids into surrounding surface and groundwater.

Exposures of aquatic life to benzocaine residues as a result of wastewater effluent discharges were determined to be *de minimis* because of (1) spatial and temporal variability of the excreted residues throughout the US, and (2) additional degradation and/or transformation and removal of benzocaine residues in wastewater treatment facilities, and (3) low consumption rates of fish in the US compared to most other types of meats consumed in the US. Further, benzocaine residues are not expected in the consumed tissues due to rapid depletion by the fish (within 24 hours).

Exposures to benzocaine resulting from application of solid residues (biosolids) from wastewater treatment to soil were also determined to be *de minimis* for the reasons described above for wastewater discharges, as well as considerable dilution in biosolids and then soil.

In addition to the landfill and wastewater pathways, the EA also evaluates exposure and risk to the US environment resulting from use of benzocaine on Atlantic salmon and rainbow trout in foreign countries where the drug is legally authorized or may become legally authorized in the future. This includes locations in close proximity to the US border (e.g., use in Canada near the US/Canadian border). Based on the use pattern described in the EA (i.e., in tanks maintained on land, and it is not expected to be used continuously), there would be spatial and temporal variability of the release of benzocaine into waters. Any benzocaine released would have to travel a large distance to impact non-target species in the US. During that time, exposure to non-target species in the US would be further reduced or eliminated due to substantial dilution and other physical and chemical processes. In addition, it is expected that an environmental evaluation of benzocaine would be conducted by the regulatory agencies in countries choosing to authorize the use of benzocaine (e.g., Canada) to determine if environmental impacts would be likely to occur, and that the country would not authorize the use of a drug that would cause significant impacts. Therefore, it is unlikely there will be significant environmental impacts in the country of use, and thus, there should be no significant environmental impacts from this use on the US environment.

Based on the information in the EA, it is concluded that establishing an import tolerance for benzocaine in Atlantic salmon and rainbow trout is not expected to have a significant impact on the environment of the US.

{ see appended electronic signature page }

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Signing Authority (Role)	Letter Date
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