

## Priority Data Gaps Regarding Animal Drugs to Treat and Prevent New World Screwworm

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### Background

FDA is committed to using the best available data to review the safety and efficacy of animal drugs to treat or prevent New World screwworm (NWS) myiasis (i.e., larvae infestation). FDA understands the importance of having legally marketed animal drug products for use in multiple species, including food-producing animals, companion animals, and wildlife that may be affected by NWS myiasis. In addition, FDA has heard from partners about the need for dosage forms, routes of administration, and drug delivery systems that make administration of drugs more practical in hard-to-treat species.

FDA has been working with international counterparts and animal drug sponsors and is reviewing scientific literature to help identify existing information about safety and effectiveness of various products. Data gaps in effectiveness, animal safety and human food safety currently exist. This may limit the availability of products for producers, veterinarians and owners in certain species and scenarios.

While not a comprehensive list, we are identifying several data gaps that, from an FDA perspective, are the most pressing. Research in these areas would better enable FDA to assess effectiveness of various animal drugs in different species, which may support FDA regulatory decisions.

FDA looks forward to working with academic, federal, state, and industry partners to advance high- priority research related to animal drugs to treat or prevent NWS myiasis.

### FDA Research Priorities for Animal Drugs for NWS Myiasis

- For various drug products/species, determine the drug concentration profile at the site of larval infestation (subcutaneous and muscle tissue) necessary for effectiveness (prevention or treatment), and correlate these tissue concentrations with plasma concentration profiles. Information in species for which there is effectiveness data and pharmacokinetic/pharmacodynamic (PK/PD) data will help extrapolate to other species where there may be more limited information.

- Validate *in vitro* models to screen drug products against current NWS larval isolates and determine susceptibilities of different larval instars. *In vitro* data could be combined with pharmacokinetic (PK) data, tissue data, and/or controlled field studies in target animals to help meet FDA requirements for animal drug approval, conditional approval, or emergency use authorization.
- Conduct clinical studies in NWS endemic areas to demonstrate effectiveness of drugs against current NWS isolates for the prevention (including prevention of reinfestations, if applicable) and treatment of NWS myiasis, especially for species for which there are currently no approved or authorized drug products.
- Develop drug delivery systems to address unmet needs for animal species that cannot be individually handled for drug administration.

### **FDA NWS Research Actions**

FDA is committed to working with academic, federal, state, and industry partners to facilitate research to fill these priority data needs. For example, FDA is working with U.S. Department of Agriculture partners on intramural and extramural opportunities to collaborate on research needs.

Resources permitting, FDA may be able to provide technical assistance on academic, federal, state, or industry partner NWS research proposals. To inquire about technical assistance, please contact FDA at [AnimalDrugNWS@fda.hhs.gov](mailto:AnimalDrugNWS@fda.hhs.gov).

At this time, FDA is unable to fund research in the areas described in this document.