new animal drug application to the FDA? (i.e a process analogous to the "am I regulated" letter that goes to APHIS for edited plants?)

- Could the FDA please clarify exactly what hazards they are anticipating that are uniquely associated with intentional genetic alterations that introduce no novel DNA sequences, and how they suggest off target alterations should be distinguished from spontaneous mutations and sequencing errors?

9. Why has the Aquabounty issues not been resolved and how will they be resolved? How will such delaying tactics aimed at FDA decisions be avoided in the future?

QUESTIONS FOR AWARDEES

10. For those persons conducting research on genetically engineered or gene edited animals, have you contacted the FDA Center for Veterinary Medicine with regard to opening an Investigational New Animal Drug (INAD) file or a Veterinary Master File (VMF)?

11. Are there areas of research/development you avoid due to the state of regulations of biotech products? Examples?