N-141454-C-0002-CP

AquaBounty Technologies, Inc.
Attention: Mark Walton, PhD
Global Director, Regulatory Affairs
2 Mill and Main Place, Suite 395
Maynard, MA 01754

Re: Request for supplemental approval, NADA 141-454

Dear Dr. Walton:

We approve your supplemental new animal drug application (NADA), dated December 22, 2017 (as amended on March 30, and April 20, 2018), for the following:

> A single copy of the α-form *opAFP-GHc2* rDNA construct at the α-locus in the EO-1α lineage of triploid, hemizygous, all-female Atlantic salmon (*Salmo* salar) known as AquAdvantage Salmon.

In this submission, you requested approval of an additional grow out facility for AquAdvantage Salmon, located in Albany, Indiana.

The specific conditions of the NADA approval on November 19, 2015, including a detailed list of record keeping and reporting requirements, were provided in Appendix A to that correspondence. We have included an amended Appendix A with the current correspondence to update the conditions of approval and record keeping/reporting requirements to incorporate the additional grow out facility in Indiana.[1] Appendix A also includes the updates you provided in your supplemental NADA relative to Section II C "Special Drug Experience Report." This was an update of the FDA offices to which the applicable reports specified in Section II C are to be directed, and a clarification of the timelines for such reports.

We remind you that deviations from the commitments and requirements described in Appendix A will result in the article being considered an unsafe new animal drug under section 512(a) of the FD&C Act and, therefore, an adulterated drug under section 501(a)(5) of the FD&C Act. Further, any food that bears or contains the article will be considered adulterated under section 402(a)(2)(C)(ii) of the FD&C Act because it bears or contains an unsafe new animal drug.

Should another firm acquire this application or otherwise become a holder of this application, that firm will be responsible for meeting all commitments and reporting requirements described in Appendix A.

[1] All references to Appendix A in the current letter are to Appendix A as amended on the date of this letter (April 26, 2018).

You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8 and as described in Appendix A. Should you wish to make any changes to the conditions established in this approval, you must consult the agency prior to doing so as described in Appendix A to determine whether a supplemental application will be required.

All other conditions of approval, covered by the approval letter for the original application dated November 19, 2015, remain in effect.

If you submit correspondence relating to this approval, you should reference this letter by the date and the principal submission identified found at the top of this letter. If you have any questions, please contact Heather Lombardi, Team Leader, Animal Bioengineering and Cellular Therapies Team at 240-402-0685 or at heather.lombardi@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Kevin J. Greenlees, PhD, DABT
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure:

Appendix A (April 26, 2018)