

SUMMARY OF EXCEPTIONS

Exceptions to the standards and regulations under the Act for the annual reporting period October 1, 2019 – September 30, 2020 are noted below. No animals experienced detrimental health effects.

1. The IACUC approved one study protocol proposing food fasting of diabetic pigs for up to 36 hours for bioavailability/pharmacokinetic studies. Food fasting periods were extended to up to 36 hours to 1) eliminate meal induced endogenous insulins from cross-reacting with the analytical assay and 2) prevent blood glucose elevation from masking the true activity of the test insulin.

Approximately 19 pigs have experienced 36 hour fasting in relation to trials during the 2019-2020 reporting period.

2. The IACUC approved one study protocol proposing food fasting of dogs for > 24 hours but not to exceed 48 hours (average of 33 hours) prior to diabetic induction procedures to ensure low levels of glycogen in the liver as it may interfere with the efficacy of the induction agent.

Approximately 10 dogs have experienced extended fasting during the 2019-2020 reporting period.