

Summary Information Format for Conventional Live Veterinary Biologics

I. INTRODUCTION

- A. Objective
- B. Proposal

II. CHARACTERIZATION OF THE MICROORGANISM

A. Microbiological Properties

- 1. Parental microorganism:
 - (a) Identity of parental strain:
 - (b) Genetic markers:
- 2. Development of the vaccine strain:
 - (a) Procedures used to attenuate the parental strain:
 - (b) Screening methods and protocols for the identification and purification of the vaccine microorganism:
 - (c) Vaccine Production
- 3. Characterization of the Master Seed:
 - (a) Master Seed designation:
 - (b) Methods and protocols used to establish identification of the Master Seed:
 - (c) Stability of the Master Seed organism at passage levels n and n+5 (or highest passage level used in production):

B. Biological Properties

- 1. Parental microorganism:
 - (a) Virulence:

- (b) Tissue tropism in susceptible host(s):
- (c) Horizontal gene transfer/recombination potential:
- (d) Host range specificity:
- (e) Environmental distribution:
- (f) Geographical distribution:
- (g) Recommended CDC/NIH biosafety levels:

2. Master Seed:

- (a) Virulence:
 - (i) Target animal:
 - (ii) Non-Target animals:
- (b) Purity:
- (c) Phenotypic stability:
- (d) Tissue tropism in susceptible host(s):
- (e) Horizontal gene transfer/recombination potential:
- (f) Shed/Spread capabilities:
- (g) Host range specificity:
- (h) Effect of overdosing:
- (i) Survivability of the microorganism in the environment:
- (j) Environmental distribution: