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: