Summary Information Format
Category I Veterinary Biologics

I. Introduction

A. Objective

1. Identify where the Regulated Biological Agent was constructed and where the product will be made, tested and manufactured. Address the available level of containment.

2. Provide a brief (one sentence) description of the Regulated Biological Agent.

B. Proposal

1. What is the intended use of the product?

a. Species:
b. Proposed claim:
c. Geographic area:
d. Route of administration:
e. Brief description of the expected safety profile:

II. Description of the Regulated Biological Agent Construction

A. The Backbone Biological Agent

1. What organism was used for the Backbone Biological Agent? Are there any known virulence features associated with the Backbone Biological Agent? What happens in the target species? [Add scientific citations, if appropriate.]

a. What is the previous safe use of the Backbone Biological Agent?

(i) If available, provide history of previous safe use, using published literature or internal documents. Include the recommended CDC/NIH biosafety level for use of the Backbone Biological Agent. [This may be the first document on safe use of the Backbone Biological Agent.]

2. Physical characteristics of the Backbone Agent

    a. Provide a flow diagram or explanation of the process of how the Backbone Biological Agent was constructed

        (i) Describe the proposed site for Donor DNA insertion.
        (ii) Do the flanking regions of the proposed insertion site in the Backbone Biological Agent have any known regulatory elements that could moderate the expression of the inserted donor DNA?
        (iii) Identify unique restriction endonucleases (not more than five) that will give identifiable digestion patterns useful for characterizing the final Backbone DNA.

B. Donor Biological Agents and Donor DNA or Genes

1. What are the Donor Biological Agents used as the source of each Donor DNA sequence inserted into the Backbone Biological Agent?

    a. Has there been safe use of the Donor Sequences or Donor Genes, as well as Safe use of the Donor Biological Agent?

        (i) Provide relevant references for safe use.

    b. Are there specific parts of the Donor Gene(s) or Sequences that were used for insertion? Show pertinent sequences or restriction endonuclease sites.

C. Construction and Characterization of the Regulated Biological Agent

1. Provide a flow diagram on the construction of the Regulated Biological Agent.

    Include the following:

    a. Final Backbone Biological Agent
    b. Donor DNA or gene
    c. All shuttle vectors
    d. Host cell lines used
    e. Selection techniques and methods used to construct the final Regulated Biological Agent

2. Describe the laboratory methods or criteria used to evaluate the Regulated Biological Agent.

3. Physical characterization of the Regulated Biological Agent

    a. Characterize the physical map, using unique Donor DNA and Backbone Biological Agent restriction endonuclease sites, and describe resulting restriction fragments and digestion patterns.

    b. Devise a PCR or restriction endonuclease test based on the Backbone Biological Agent sequence and the Donor Sequence that will identify and characterize the Donor DNA/Backbone Biological Agent construct.

    c. What will be the criteria for stability and purity of the Regulated Biological Agent Master Seed n and n+5?

    d. Provide the genetic sequence in electronic format for any new or altered genetic sequences, including insertion and flanking sequences.

4. What is the recommended CDC/NIH biosafety level for the Regulated Biological Agent?

5. Provide a short summary or description of genetic motifs that may have resulted as a consequence of the genetic recombination (II.C.3.d). Are there any known motifs that may promote homologous recombination, DNA insertion, or gene expression of existing or new open reading frames?