Policy, Evaluation, and Licensing Unit

Last Modified:

Policy, Evaluation, and Licensing (PEL) is a unit in the Center for Veterinary Biologics (CVB). The licensing staff within CVB-PEL reviews license applications for production facilities and biological products; reviews applications for permits for importation of products; establishes licensing, testing, and permit requirements and procedures; and reviews production methods, labels, and supporting data involved in the licensing and permit process.

The laboratory staff within CVB-PEL conducts assays on veterinary biological products. Primary activities include:

1. prelicense testing,
2. test development and standardization (including reagent activities), and
3. postlicense quality control monitoring.

Prelicense testing includes assaying parent materials (master seeds and cells) and final product. Master seeds and master cell stocks are evaluated for purity and identity (including identity of construct and expressed antigen for genetically engineered products). Initial (usually three) serials (i.e., numbered batches) of product are tested for purity, safety, and potency to assure that the product tests are appropriate and transferable and that the manufacturer is able to make quality product reproducibly.

Reference and reagent development, production, characterization, and distribution are important standardization activities often best performed by a central laboratory. Reference micro-organisms and standards, antisera, monoclonal antibodies, fluorescent antibody conjugates, and other biological reagents are provided to manufacturers for use in their in-vitro and in-vivo (e.g., vaccination-challenge) testing. Standards may be used for direct or indirect potency comparisons or for independent efficacy, identity, and purity testing.

Samples of each serial of all licensed veterinary biologics are submitted to the CVB-PEL by the manufacturer and are stored for the shelf life of the product. All serials are required to be tested by the manufacturer prior to sale. The reliability of the manufacturer's quality control program is monitored by confirmatory testing of randomly selected serials by the CVB-PEL. Marketed product also may be tested as part of an investigation resulting from consumer or manufacturer concerns.

The CVB, as a regulatory entity, is not involved in fundamental research. It is involved in applied research or developmental activities related to veterinary biologics issues. The activities involve learning techniques needed to evaluate new products (e.g., vectored immunogens), developing new tests and reagents (e.g., *in vitro* antigen quantitation assays), and examining safety issues (e.g., virulence markers). Special emphasis is placed on reducing or replacing animal use and suffering in veterinary biologics evaluation.

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