10.0   Animal Welfare Considerations

10.1   How the rLLNA will Refine, Reduce, or Replace Animal Use

Compared to the traditional LLNA, the rLLNA will reduce the number of animals used to assess skin sensitization. In addition to a concurrent vehicle-control group and a positive-control group, the traditional LLNA requires testing four to five mice with each of at least three test-substance dose levels (ICCVAM 1999). Because the rLLNA tests only the highest dose level of the test substance being evaluated, in addition to the concurrent control groups, the number of animals tested would be decreased by at least 40% for each test.

10.2   Requirements for the Use of Animals

The rationale for the use of animals and the basis for determining the number of animals used in the rLLNA are the same as those for the traditional LLNA (ICCVAM 1999).