E13

The 3767 rats assigned to column E of this report were included in toxicology/safety assessment procedures or evaluations of the immunologic effects of compounds.

1326 rats were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) a defined number of animals must be exposed to test compound at dose levels toxic to the animal. Clinical signs produced by some test compounds at toxic levels may be distressful or painful to the animal, if only transiently. To intercede prematurely would invalidate the procedure under the cited regulations, requiring repetition of the study and the consequent use of more animals.

2441 rats were used to evaluate the immunologic activity of the test compounds. Animals in test or positive control groups experience, associated with the immune response, inflammation that could be painful or uncomfortable yet cannot be relieved with drugs that could interfere with the phenomena being evaluated. Such discomfort was alleviated as soon as could be scientifically justified without invalidating the results of the procedure.

E13

Mice assigned to Column E of this report were used in various toxicology/safety assessment procedures, pharmacologic studies of inflammatory response or evaluation of the immunologic effects of compounds.

1396 mice were included in toxicology or safety assessment procedures in which to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) a defined number of animals must be exposed to test compound at dose levels toxic to the animal. Clinical signs produced by some test compounds at toxic levels may be distressful or painful to the animal, if only transiently. To intercede prematurely would invalidate the procedure under the cited regulations, requiring repetition of the study and the consequent use of more animals.

20,849 mice were used in experimental procedures designed to assess the various immunologic effects of test compounds. Animals in the test or positive control groups experience, associated with the various immune responses, manifestations of the inflammatory response which could be painful or uncomfortable yet could not be relieved with drugs that could interfere with the phenomena being evaluated. Such discomfort was alleviated as soon as could be scientifically justified without invalidating the results of the procedure.

25 mice were used for the production of immune proteins or inflammatory cells which are essential reagents of several in vitro tests, which are used to screen compounds for activity or to evaluate mechanisms and which replace live animals.