

Protocol

I. Intramuscular injections

1. Duration of test: 30 days
2. Animals used:
 - a. Rats: 3 test groups of 20 animals each and one control group of 20 animals
 - b. Dogs: 3 test groups of 6 animals each and one control group of 6 animals
3. Necropsy: Gross and microscopic studies on major organs of all animals at completion of test
4. Other studies: Complete blood counts on all animals at beginning and end of test period. Liver and kidney function tests on all dogs (Method and frequency undefined.)

II. Local irritation

1. Method: Two injections at same time in each of 10 rabbits, using the sacrospinalis muscle as the site. Sacrifice all animals after five days observation, remove the injected muscles and examine for evidence of irritation.

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B.F. Goodrich

The B.F. Goodrich Company

November 8, 1961

500 So. Main St.
Akron 18, Ohio
253-1171

Dr. R.A. Kehoe
Kettering Laboratory
College of Medicine
Cincinnati 19, Ohio

Dear Doctor Kehoe:

We are considering the performance of some animal toxicology on a polymer with the intent of ultimately supporting a new drug application. Extensive oral toxicology already exists on the material. The protocol of the studies is enclosed.

I would appreciate your advising me if you are interested in performing these studies for us, and their cost.

Very truly yours,

W.E. McCormick
W.E. McCormick, Manager
Department of Industrial
Hygiene and Toxicology

~ 15,

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