Registration Number: 22-R-0082

Attachment to USDA/APHIS Annual Report of Research facility

Explanation of Column "E" Entries.

10/01/09 through 9/30/10

413 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600):
405 of these were used from Magnusson & Kligman method studies and 8 were from Buehler method studies. These animals exhibited eschar and/or corrosion at the dose site, which may indicate necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was ≤ 1 in^2. Use of topical anesthetic agents during dermal irritation tests is deemed inappropriate as it could lead to study complications such as delayed healing of the test site and likely impact the level of irritation (increase or decrease) which would result in questionable results. The use of analgesics in these particular studies would be inappropriate as well due to the resultant anti-inflammatory effects that could mask the indicators of irritation. The use of either of these agents could significantly compromise the results of the study.

22 Hamsters – Reversal of Dyslipidemia study in Hamsters:
The doses of reference agent used caused unexpected toxicity in 22 subjects which was severe enough to negate the potential effects of the test agent, in some cases causing lethality. After careful consideration, the study was terminated and the animals euthanized humanely.

26 Ferrets – Potential Emetic activity in ferrets
All ferrets that show signs of emesis or pro-emetic activity are assumed to be experiencing distress. The presence, quantity and duration of the emetic episodes are the endpoint for the study and the use of any type of calming agent, anti-emetic or other drug to reduce or prevent this behavior would clearly have a direct impact on the outcome of the study.

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