

[REDACTED]
 Regulatory Affairs Manager
 Nufarm UK Limited
 Wyke Lane
 Wyke
 Bradford
 BD12 9EJ
 United Kingdom

Re: Historical Incidence of Malignant lymphoma in CD-1 Mouse.

Dear [REDACTED],

I am writing to provide supporting information that I consider can be used as further data for evaluation of rates of lymphoreticular tumours in the CD-1 Mouse from our control database within [REDACTED] of testing laboratories in Europe. This data would have been generated from standard Toxicology studies according to the appropriate test guidelines that were in force at the time of study conduct. The studies would also have been conducted to meet the standards set to meet the OECD principles of Good Laboratory Practice (or national equivalent). Due to the frequency and nature of such studies these data would have been collated over a period of time (2000 to 2010) and may therefore be regarded as contemporaneous. These data may therefore be viewed as further support to the findings from the concurrent control group (from; Glyphosate Technical: Dietary Carcenogenicity Study in the mouse, [REDACTED] Project number 2060-0011) plus other published data from the animal supplier.

The data have been collated and presented in Table 1.

Table 1 - Historical control data for Lymphoreticular tumours in CD-1 Mouse 2000-2010

Hemolymphoreticular System

Males	1	2	3	4	5	6	7	8	9	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of mice examined after 104 weeks	100	130	100	68	100	50	66	104	50	768					
Histiocytic sarcoma	6	5	0	0	0	1	11	0	0	23	4.61	4.59	6.38	0.00	16.67
Malignant lymphoma	7	17	9	0	14	16	0	0	0	63	12.63	7.51	6.61	0.00	32.00
Mast cell tumor (m)	0	0	0	0	0	1	0	0	0	1	0.20	0.17	0.41	0.00	1.00
Plasmacytoma	0	0	0	0	0	0	0	0	0	0	0.00	0.00	0.00	0.00	0.00
Myeloid leukemia	0	0	1	0	0	0	0	0	0	1	0.20	0.17	0.41	0.00	1.00
Sarcoma histiocytic	0	0	1	0	0	0	0	0	0	1	0.20	0.17	0.41	0.00	1.00
Lymphoma: NOS	0	0	0	0	0	0	0	0	0	0	0.00	0.00	0.00	0.00	0.00

[REDACTED]



Females	1	2	3	4	5	6	7	8	9	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of mice examined After 104 weeks	100	130	100	68	100	50	62	104	50	764					
Histiocytic sarcoma	1	6	0	3	0	6	0	0	0	16	3.15	5.26	7.64	0.00	20.00
Malignant lymphoma	19	43	25	0	28	31	0	0	0	146	28.74	17.97	14.74	0.00	62.00
Mast cell tumor (m)	0	0	0	0	0	0	0	0	0	0	0.00	0.00	0.00	0.00	0.00
Plasmacytoma	0	1	0	0	0	0	0	0	0	1	0.20	0.13	0.31	0.00	0.76
Myeloid leukemia	0	0	2	0	0	2	0	0	0	4	0.79	0.67	1.03	0.00	2.00
Sarcoma histiocytic	0	0	4	0	9	0	0	0	0	13	2.56	0.67	1.63	0.00	4.00
Lymphoma: NOS	0	0	0	0	0	0	29	0	0	29	5.71	7.80	19.10	0.00	46.77

I hope this information is of use to you.

Kind Regards



Head of Toxicology

