

| Section of FDA Briefing Book | Page Number | Comment |
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| 2- Pharmacology/Toxicology Review | 5 of 18 (Table 3) | Amend footnote to read "Shaded values (yellow) were above concurrent and historical control group range for skin and subcutis fibrosarcomas (0-7.5% in males, 0-10% in females) and sarcomas not otherwise specified (0-2% in males, 0-8% in females). The historical control group incidence for injection site fibrosarcomas was 0% in males and females." |
| | 8 of 18 | The sentence should read "...rats treated for 4 weeks with 0.75 mg/kg/day (BrdU labeling calcitonin immunoreactive cells), rats treated for 26 weeks with 1 mg/kg/day (colocalization of PCNA and calcitonin immunoreactivities), or monkeys treated for 52 weeks with 5 mg/kg/day (colocalization of PCNA and calcitonin immunoreactivities). |
| | 11 of 18 | Focal hyperplasia occurring after 9 weeks wasn't fully reversed after a 15 week recovery period (focal c-cell hyperplasia persisted in 1 high dose female mouse). |
| | 15 of 18 | Add the following reference to the reference list on pages 17 – 18 "Knostman KA, Jhiang SM, Capen CC. Genetic alterations in thyroid cancer: the role of mouse models Vet Pathol. 2007 Jan;44(1):1-14" |
| 3 -Joint Clinical/Statistical Review | 2 of 100 | Sentence should read "As of the date of submission of the NDA (23 May 2008)..." |
| | 7 of 100 | Table LB.I, footnote 1 should read "Status at time of NDA submission (23 May 2008)." |
| | 7 of 100 | Sentence should read "Two Phase 1 trials explored alternate routes of administration; intranasal in NN9233-1898 and pulmonary in NN2211-1464." Sentence should read "At the time of NDA submission, there were also six ongoing trials including extensions of NN2211-1572 and NN2211-1573." |
| | 23 of 100 | Trial NN8022-1807 is mentioned twice in the same sentence. |
| | 25 of 100 | Sentence should read "Based on Novo's analyses, all 12 point estimates for the incidence ratio of LGT vs total comparator were <1.0 and 12 of the 12 of the estimated upper 95% CI bounds were <1.8. |
| | 37 of 100 | Table ILC.9 Population A is used, but not specified in the title |
| | 55 of 100 | Table II.C.15 the FDA Custom Total Comparator N should be 13 instead of 12 (sum of active + Placebo) |

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| | 80 of 100 | Correct spelling of the last name for the reference is 'De Lellis 1981'. |
| | 99 of 100 | Correct spelling of the last name for the reference is 'De Lellis 1981'. |
| 4 -Statistical Review of Efficacy | 35 of 60 | Sentence should read "The smaller effect may be due to the population of Trial 1436 which included patients in reasonable glyceic control." |