

FARAD NEWSLETTER # 4 - CLARIFICATION

In the newsletter transmitted last week the item concerning Banamine® [NADA 101-479] receiving a supplemental approval for use in lactating dairy cows has confused some of our readers. Despair not – the wording quoted directly from the Federal Register notice of Schering Plough being awarded a supplementary claim for use of their product, Banamine®, in lactating dairy cattle was correct but, to most of us, did not make it clear that it related only to the Schering Plough preparation and not to the generic versions of flunixin meglumine [ANADA's 200-308, 200-124, & 200-061]. The significance of this differentiation is that Banamine® is the only flunixin formulation approved for use in lactating dairy cattle during the period of exclusivity granted by the FDA in recognition of the Sponsor's successful application. The labels of the generic flunixin will continue to contain the statement "Not for use in lactating or dry dairy cows". Extralabel use of these generics in lactating dairy cows is not permitted under AMDUCA as Banamine® has an approved label permitting its use in lactating dairy cows.

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