

Attachment II

Benzocaine Feedback Meeting 28 June 2004

Meeting Questions

1. Does the Agency agree with the proposed OTC labels (Del Pharmaceuticals and Wyeth Consumer Healthcare) for benzocaine-containing products marketed for toothache?
 - a. Does the Agency agree that the direction for the amount of product to use is sufficiently clear that the consumer will apply the appropriate dose of the product?
 - b. Does the Agency agree that benzocaine may be used up to 4 times daily but not more often than every 2 hours, or as directed by a dentist or physician?

2. Based on our review of the updated safety assessment and literature reports of methemoglobinemia associated with the use of benzocaine-containing products for toothache, we conclude methemoglobinemia is an extremely rare event. Therefore, does the Agency agree that a specific methemoglobinemia warning statement is not necessary?

3. Does the Agency agree that the results from clinical study BZ-03-08, in conjunction with results of previous Del clinical studies which evaluated the efficacy of both 10% and 20% benzocaine, are sufficient to establish monograph status for toothache, and therefore no additional clinical study is necessary?

4. If the Agency requires an additional efficacy study with 10% and 20% benzocaine, does the Agency agree the attached protocol is adequate to demonstrate the efficacy for both 10% and 20% benzocaine-containing products and fulfills the requirement for one additional study as outlined in the feedback letter dated 29 October 2002?