

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Center for Biologics Evaluation and Research**  
**Division of Bacterial, Parasitic, and Allergenic Products (DBPAP)**

**Date:** 19 October 2006

**From:** Jay E. Slater, MD, DBPAP

**Subject:** 103738/5031 (submission August 14, 2006)

**To:** Jennifer Ross, DVRPA

This is the supplement for the addition of a TRUE Test rubber patch panel, to include carba mix, black rubber mix, mercaptobenzothiazole, mercapto mix and thiuram mix, as well as a negative control patch. These are responses to our letter of 30 June 2006. Comments intended for transmittal to the sponsor are in **bold**.

1. Sponsor notes that the existing specification for (b) (4) analyses is for process validation only. This response is acceptable.
2. **The commitment to perform stability studies through 24 months on the first three commercial batches is noted. We note as well that “[t]he rubber panel has not yet been produced.” Please acknowledge that three production lots will need to be produced prior to approval. We understand that you have acquired stability data on the component patches in configurations other than those proposed in this supplement, and that this information may be useful in providing an initial estimate for expiry of the approved product. However, we reiterate that final expiry dating will be based upon real-time stability data of these batches. Please acknowledge.**
3. [Lot release protocol to be reviewed by OCBQ]
4. This response is acceptable. (b) (4) results should be reviewed by OCBQ as well].
5. This response is acceptable.
6. This response is acceptable.