

**Koenig, Michael**

**From:** Navarro Lisa PA US [lisa.navarro@cibasc.com]  
**Sent:** Monday, August 08, 2005 11:41 AM  
**To:** Koenig, Michael  
**Cc:** Ochs Dietmar PA DE; Osterwalder Uli PA CH  
**Subject:** RE: Confidential information in bisoctrizole and bemotrizinol TEAs

Will the final TEAs be in the electronic docket room or only in paper form requiring people to visit the docket room?

Per our understanding and agreement for both Bemotrizinol and Bisoctrizole:

- Section 2.7 (information inside the purple boxes): THIS INFORMATION WILL REMAIN CONFIDENTIAL.
  - Table 7 in Section 3.4 (information inside the purple box other than the information in the cells identifying the row "TOTAL (7 countries)" and the column "Total Volume 2000-2004 (KGS.)" and the contents of the cell at the intersection of that row and column). THE INFORMATION IN THE SINGLE CELL IDENTIFIED AND THE HEADINGS FOR THE CORRESPONDING ROW AND COLUMN MAY BE DISCLOSED, ALL OTHER DATA IN THIS TABLE WILL REMAIN CONFIDENTIAL.
  - Table 8 in Section 3.4 (information inside the purple box other than the information in the cells identifying the row "TOTAL (7 countries)" and the column "Total Number of Units (x 1000) 2000-2004" and the contents of the cell at the intersection of that row and column). THE INFORMATION IN THE SINGLE CELL IDENTIFIED AND THE HEADINGS FOR THE CORRESPONDING ROW AND COLUMN MAY BE DISCLOSED, ALL OTHER DATA IN THIS TABLE WILL REMAIN CONFIDENTIAL.
  - Table 9 in Section 3.4 (information inside the purple box other than the information in the cells identifying the row "TOTAL (7 countries)" and the column "Total Application Number (Million) 2000-2004," and the contents of the cell at the intersection of that row and column. THE INFORMATION IN THE SINGLE CELL IDENTIFIED AND THE HEADINGS FOR THE CORRESPONDING ROW AND COLUMN MAY BE DISCLOSED, ALL OTHER DATA IN THIS TABLE WILL REMAIN CONFIDENTIAL.
- Appendix II (tables enclosed within blue boxes) THIS INFORMATION WILL REMAIN CONFIDENTIAL

Thanks.  
Lisa

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**From:** Koenig, Michael [mailto:KoenigM@cder.fda.gov]  
8/8/2005