Appendix B

Summary Counts for Ketek Related Adverse Event Reports Submitted to the Adverse Event Reporting System (AERS)*
July 2005 to September 2005[1]

- **Deaths: 2**
- **Total Liver Adverse Events: 35**
- Liver transplant - 1
- Liver disorder - 2
- Liver function test abnormal - 2
- Liver scan abnormal - 2
- Hepatic failure - 2
- Hepatic function abnormal - 2
- Hepatic pain - 1
- Hepatic enzyme increased - 7
- Hepatic trauma - 1
- Hepatic streatosis - 1
- Hepatitis - 4
- Hepatitis acute - 1
- Hepatitis fulminant - 2
- Jaundice – 7
- Hyperbilirubinaemia - 1
- **Total Cardiac Adverse Events: 44**
- Cardiac failure - 2
- Cardiac arrest - 1
- Cardiac disorder - 1
- Electrocardiogram change - 1
- Electrocardiogram QT corrected interval prolonged - 2
- Electrocardiogram abnormal - 1
- Electrocardiogram poor r-wave progression - 1
- Heart rate increase - 5
- Heart rate irregular - 2
- Palpitations - 8
- Chest pain – 12
- Supraventricular tachycardia -1
- Ventricular tachycardia - 2
- Tachycardia – 4
- Myocardial ischaemia - 1
- **Total Visual Adverse Events: 80**

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[1] See http://www.fda.gov/cder/aers/extract.htm

- Visual disturbances - 16
- Visual brightness - 3
- Visual field defect - 1
- Vision blurred - 40
- Blindness transient - 2
- Blindness - 1
- Ocular hyperaemia - 2
- Ocular icterus - 2
- Ocular eye movement disorder - 1
- Eye movement disorder - 1
- Eye swelling - 1
- Eye irritation - 1
- Eyelid disorder - 1
- Eye pain - 3
- Abnormal sensation in eye - 2
- Eye pruritis -1
- Binocular eye movement disorder - 1
- Photopsia - 1
- **Embolism - 1**
- **Convulsions - 7**
- **Loss of consciousness - 9**
- **Multiple Sclerosis - 1**
- **Anaphylactic reaction – 3**

* There are some important things to keep in mind when reviewing or analyzing AERS data:

"For any given report, there is no certainty that a suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions; however, the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or simply occurred by chance at that time.

Accumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate drug risk. Comparisons between drugs cannot be made from these data."[2] For more information regarding the FDA's Adverse Event Reporting system, please go to: http://www.fda.gov/cder/aers/default.htm

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[2] FDA "README.DOC" File for Quarterly Data Extract from the ADVERSE EVENT REPORTING SYSTEM (AERS), Revised March 8, 2006