

SUBMISSION FOR THE OPHTHALMIC DEVICES ADVISORY COMMITTEE MEETING JUNE 10, 2008

- Multi-purpose contact lens care solutions (MPS) should be more tightly regulated by the FDA to reduce patient injuries.
- The recent B&L and AMO recalls, lawsuits by seriously injured patients, Medical Journal Articles, news reports, studies showing poor compliance with prescribed lens care regimens all suggest that MPS products are more hazardous than claimed by the industry.
- Considering that poor compliance with MPS regimens is well known and that a substantial portion of contact lens users are children, sales cannot be justified by blaming keratitis on the victims.
- MPS manufacturers claim that safety is demonstrated by the alleged low number of keratitis cases. However, comprehensive post market records of problems are not kept by manufacturers or government agencies. The two recent MPS recalls were instigated by Singapore where records are kept. An important first step in controlling MPS hazards would be to institute a national post market problem registry.
- An appropriate bold hazard warning should be added to MPS labels.
- Acanthamoeba should be added to the MPS test protocol. The Fusarium test should be improved as it apparently failed in the B&L Moisture Loc case.
- Rub and rinse steps should again be required for MPS.
- Ideally, MPS should be banned as there are safer hydrogen peroxide products available on the market.

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