

**MEMORANDUM DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

DATE: October 2, 2007

TO: The Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee

FROM: FDA

SUBJECT: **Errata to FDA Background document for the advisory committee meeting on October 18 & 19, 2007**

The Division of Drug Risk Evaluation (DDRE) provides these corrections to the original background package submitted for the Joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee meeting scheduled for October 18 & 19, 2007.

The following items in the FDA Background volume 1, 2nd Safety Review need to be corrected. Deletions are indicated by strikethrough and corrections are in italics.

Page 3, first bullet, 3rd & 4th sub-bullets:

- Approximately ~~16%~~ *9%* of the cases reported a medication error that resulted in a serious adverse event to include prescribing errors, dispensing errors, administration errors, duplication of therapy, and wrong drug administration.
- The manner of overdose could not be determined in ~~the remaining 56%~~ *11%* of the cases.

Page 53, seventh bullet, 3rd & 4th sub-bullets:

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- The manner of overdose could not be determined in ~~the remaining 56%~~ *11%* of the cases.