8.7.3 Complaint files

Written procedures shall be established and followed for the handling of all written and oral product complaints. Such procedures shall provide for review by the quality control unit and determination of the need for an investigation.

A written record of each complaint shall be maintained for at least one year after the expiration or shelf life date of the product, or one year after the date that the complaint was received, whichever is longer. The written record shall include, where known, the name and description of the product, lot number, source and nature of the complaint, and response, if any. When an investigation is conducted, the written record shall include the findings of the investigation and follow-up action taken.

On and forward from the effective date for this regulation, written procedures shall be established and followed for reporting adverse events to the FDA in accordance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act.

ANNEX D
(informative)

The effective date for compliance for the Dietary Supplement and Non-Prescription Drug Consumer Protection Act in Section 8.7.3 will be effective December 22, 2007.