

Appendix A. LEVEL OF DEFECT

Class I Recall

The product may harm the consumer for any of the following reasons:

- Presence of contaminants or toxins in critical amounts.
- Presence of pathogenic micro-organisms.
- Non-integrity of packaging.
- Presence of undeclared critical allergens.
- Packaging error (e.g. milk powder in infant formula pack).
- Product tampering and adulteration.
- Presence of broken glass or other foreign bodies that may harm the consumer.

Class II Recall

The product has a serious organoleptic defect or does not comply with federal regulations in respect to any of the following:

- Labeling.
- Packaging.
- Composition (ingredients).
- Contains pesticides, mycotoxins, veterinary drug residues, heavy metals, nitrates, or other contaminants in excess of regulatory limits.
- Falls outside the norms for food additives.
- Falls outside microbiological norms (excluding pathogens).
- Net weight.
- Nutritional claims.

Class III –or– Market Withdrawal

The product complies fully with FDA regulations, but does not meet company internal quality standards in respect to any of the following:

- Composition.
- Microbiological quality.
- Physical properties (solubility, wettability).
- Appearance (e.g. color, texture, foreign bodies).
- Labeling.
- Packaging.
- Physical appearance of the pack or shipping carton/case.
- Organoleptic defect.