Subpart N—Returned Dietary Supplements

§ 111.503 What are the requirements under this subpart N for written procedures?
You must establish and follow written procedures to fulfill the requirements of this subpart.

§ 111.510 What requirements apply when a returned dietary supplement is received?
You must identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision.

§ 111.515 When must a returned dietary supplement be destroyed, or otherwise suitably disposed of?
You must destroy, or otherwise suitably dispose of, any returned dietary supplement unless the outcome of a material review and disposition decision is that quality control personnel do the following:
(a) Approve the salvage of the returned dietary supplement for redistribution or
(b) Approve the returned dietary supplement for reprocessing.

§ 111.520 When may a returned dietary supplement be salvaged?
You may salvage a returned dietary supplement only if quality control personnel conduct a material review and make a disposition decision to allow the salvage.

§ 111.525 What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing?
(a) You must ensure that any reprocessed dietary supplements that are reprocessed meet all product specifications established in accordance with §111.70(e); and
(b) Quality control personnel must approve or reject the release for distribution of any returned dietary supplement that is reprocessed.

Subpart O—Product Complaints

§ 111.553 What are the requirements under this subpart O for written procedures?
You must establish and follow written procedures to fulfill the requirements of this subpart O.

§ 111.560 What requirements apply to the review and investigation of a product complaint?
(a) A qualified person must:
(1) Review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury; and