**Section 725.71 Drug Product Salvaging**

Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace pursuant to this Part. Improper storage conditions include, but are not limited to, variations in temperature extremes, moisture permeation or conditions of high humidity, potential exposure of the product to the environment, insanitary storage conditions, or infestation with insects or vermin. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is evidence from laboratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident (21 CFR 211.208). Organoleptic examinations shall be acceptable only as supplemental evidence that drug products meet appropriate standards of identity, strength, quality, and purity. Appropriate standards would include the specific portion of the products' monograph in the official compendia as stated in the Food, Drug and Cosmetic Act, the statutory or regulatory standard of identity, if existing, or a particular product, and the manufacturer's internal standards of product quality. Records including name, lot number, and disposition shall be maintained for drug products subject to this Section.

(Source: Amended at 14 Ill. Reg. 864, effective January 1, 1990)