Food And Drug Law: Cases And Materials

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The Food Drug and Cosmetic Act (FD&C): 501(a)(2)(b) requires conformity with CGMP. A drug shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered. Components, containers/closures, in-process materials, labeling, and drug products conform to standards of identity, purity, quality and strength.

Summary of Top 10 Cites 01 Jan to 31 Dec 2012

5. 6. 7. 8. 9. 10. (cont’d.) A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, is not a drug under clause (C) solely because the label or the labeling contains such a statement.

The amendments made to this Act by the Drug Amendments of 1962 included amendments establishing the requirement that new drugs be effective. Section 107(c) of such Public Law concerned the applicability of the amendments, and is included in the appendix to this compilation.