

(5) THE METHODS, FACILITIES, OR CONTROLS USED IN THE MANUFACTURE, PROCESSING, PACKING, OR HOLDING OF THE DRUG DO NOT CONFORM TO, OR ARE NOT ADMINISTERED IN CONFORMITY TO, GOOD PRACTICE TO ASSURE THAT THE DRUG:

(I) MEETS THE REQUIREMENTS OF THIS SUBTITLE AS TO SAFETY; AND

(II) HAS THE IDENTITY, STRENGTH, QUALITY, AND PURITY THAT IT PURPORTS TO HAVE;

(6) IT IS PURPORTED TO BE A DRUG THE NAME OF WHICH IS RECOGNIZED IN AN OFFICIAL COMPENDIUM AND:

(I) THE STRENGTH OF THE DRUG DIFFERS FROM, OR THE QUALITY OR PURITY OF THE DRUG FALLS BELOW, THE STANDARD SET IN THE OFFICIAL COMPENDIUM; AND

(II) THE DIFFERENCE IN STRENGTH, QUALITY, OR PURITY IS NOT STATED PLAINLY ON ITS LABEL; OR

(7) ALTHOUGH NOT PURPORTED TO BE A DRUG RECOGNIZED IN AN OFFICIAL COMPENDIUM, THE STRENGTH OF THE DRUG DIFFERS FROM, OR THE QUALITY OR PURITY OF THE DRUG FALLS BELOW THAT WHICH THE DRUG PURPORTS TO POSSESS.

(D) TESTING DRUGS PURPORTED TO BE RECOGNIZED IN OFFICIAL COMPENDIUM; APPLICATION OF REQUIREMENTS IN OFFICIAL COMPENDIUM.

(1) FOR PURPOSES OF ADMINISTERING SUBSECTION (C)(6) OF THIS SECTION, ANY DETERMINATION AS TO WHETHER THE STRENGTH OF A DRUG DIFFERS FROM OR AS TO WHETHER ITS QUALITY OR PURITY FALLS BELOW THE STANDARD SET IN AN OFFICIAL COMPENDIUM SHALL BE MADE IN ACCORDANCE WITH THE TESTS OR METHODS OF ASSAY SET FORTH IN THE OFFICIAL COMPENDIUM, OR, IN THE ABSENCE OF OR INADEQUACY OF THOSE TESTS OR METHODS OF ASSAY, THOSE PROVIDED UNDER THE FEDERAL ACT.

(2) (I) EXCEPT AS PROVIDED IN SUBPARAGRAPH (II) OF THIS PARAGRAPH, IF A DRUG IS RECOGNIZED IN BOTH THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY AND IN THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES, IT IS SUBJECT TO THE REQUIREMENTS OF THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY.

(II) IF THE DRUG IS LABELED AND OFFERED FOR SALE AS A HOMEOPATHIC DRUG, IT IS SUBJECT TO THE PROVISIONS OF THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES AND NOT TO THOSE OF THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY.

REVISOR'S NOTE: This section is new language derived without substantive change from former Article 43, § 189A.