In subsection (c)(2) of this section, the reference to a finding under § 4-239 of this subtitle is substituted for the reference to the Federal Act. While, ultimately, the determination of whether a color additive is to be considered safe in this State is most apt to be made under the Federal Act, that determination can be made by the Secretary under this subtitle. Section 4-239 of this subtitle sets forth the process by which a determination is made under either the Federal Act or this subtitle.

In subsection (d)(2) of this section, reference to the "United States Pharmacopeia and National Formulary" is substituted for the language that refers only to the "United States Pharmacopeia". These publications have merged since former Article 43, § 189A was enacted.

4-217. MISBRANDED DRUGS AND DEVICES.

(A) APPLICATION OF SECTIONS.

FOR PURPOSES OF THIS SUBTITLE, A DRUG OR DEVICE IS MISBRANDED IF THE STANDARDS IN THIS SECTION OR IN § 4-218 OR § 4-220(D) OR (E) OF THIS SUBTITLE APPLY.

(B) IN GENERAL.

A DRUG OR DEVICE IS MISBRANDED IF:

(1) ITS LABELING IS FALSE OR MISLEADING IN ANY WAY;

(2) ITS LABELING OR PACKAGING DOES NOT CONFORM WITH ANY PROVISION OF § 4-248 OF THIS SUBTITLE;

(3) IT IS IN PACKAGE FORM AND IT DOES NOT BEAR A LABEL THAT CONTAINS THE NAME AND PLACE OF BUSINESS OF THE MANUFACTURER, PACKER, OR DISTRIBUTOR;

(4) ANY WORD, STATEMENT, OR OTHER INFORMATION REQUIRED UNDER THIS SUBTITLE TO APPEAR ON ITS LABELING IS NOT PLACED PROMINENTLY ON THE LABELING IN A MANNER THAT IS:

(I) CONSPICUOUS AS COMPARED WITH OTHER WORDS, STATEMENTS, DESIGNS, OR SYMBOLS ON THE LABELING; AND

(II) IN TERMS LIKELY TO BE READ AND UNDERSTOOD BY THE ORDINARY INDIVIDUAL UNDER CUSTOMARY CONDITIONS OF PURCHASE AND USE;

(5) ITS LABELING DOES NOT INCLUDE, IN WHATEVER MANNER AND FORM THAT MAY BE NECESSARY TO PROTECT THE USER OF THE DRUG OR DEVICE: