

REGULATION THAT SPECIFIES HOW THE DRUG IS TO BE PACKAGED AND REQUIRES THAT ITS LABEL BEAR A STATEMENT OF PRECAUTIONS.

(II) THE SECRETARY MAY NOT ADOPT A RULE OR REGULATION UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH BEFORE THE SECRETARY HAS INFORMED THE APPROPRIATE BODY THAT IS CHARGED WITH THE REVISION OF THE OFFICIAL COMPENDIUM OF THE NEED FOR THE PACKAGING OR LABELING REQUIREMENTS AND THAT BODY HAS FAILED TO ADOPT THE REQUIREMENTS WITHIN A REASONABLE TIME.

REVISOR'S NOTE: This section is new language derived without substantive change from former Article 43, § 189B(4), (5), (8), (9), (10), (12), (13), (14), and (15).

Some of the professional people with whom the Commission to Revise the Annotated Code conferred in drafting this subtitle believe that the label requirements set forth in subsection (b)(1) of this section should apply to any prescription drug. The General Assembly, therefore, may wish to amend this section. If subsection (b)(1) is amended to apply to any prescription drug, subsection (d)(1) of this section should be repealed as unnecessary.

The provisions of former Article 43, § 189(10), revised as subsection (b)(7) through (10) of this section, were limited expressly to apply to drugs only. The revision of those provisions under this section, which applies only to drugs, retains this limited application. However, the concerns addressed by these provisions also may be applicable to devices. The General Assembly, therefore, may wish to transfer these provisions to be included under § 4-217(b) of this subtitle, which would have the effect of making the provisions applicable to both drugs and devices.

As to the reference to the Federal Act in subsection (b)(11) of this section, see 21 U.S.C. 356.

In subsection (b)(13) 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 may 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.