VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 32.1-81 of the Code of Virginia, relating to Virginia Voluntary Formulary.

[H 2029]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-81 of the Code of Virginia is amended and reenacted as follows:

§ 32.1-81. Amendments to the Formulary.

A. The Formulary Board shall ~~recommend to the State Board of Health a Formulary and any subsequent revisions or amendments to the Formulary. The State Board of Health may accept or reject some or all of the recommendations of the Formulary Board but may not otherwise revise, amend or add to such recommendations~~, *upon application, review, a determination of acceptability by the Formulary Board, and approval by the Commissioner, include drug products in the Formulary if such drugs have been approved by the federal Food and Drug Administration (FDA) with an A (therapeutically equivalent) category rating.*

B. ~~In formulating its recommendations regarding revisions or amendments to the Formulary to the State Board of Health,~~ The Formulary Board shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§ 9-6.14:1 et seq.) *when adding or deleting drug products from the Formulary*. The Formulary Board shall, however, conduct public hearings prior to ~~making such recommendations to the Board of Health~~ *listing any drug products which are not approved by the FDA with an A (therapeutically equivalent) category rating or any proposed, nonemergency deletions from the Formulary*. The Formulary Board shall give thirty days' written notice by mail of the time and place of its hearings to any manufacturer or other supplier who would be aggrieved by the Formulary Board's proposed recommendations and to those manufacturers and other suppliers who request the Formulary Board in writing that they be informed of such hearings. In addition, the Formulary Board shall give thirty days' notice of such public hearings to the public by publishing its intention to conduct hearings in the Calendar of Events of the Virginia Register of Regulations and a newspaper of general circulation located in Richmond. *Following the public hearing and, upon approval of the Commissioner, the Formulary Board may amend the Formulary.*

C. Upon notification from the Federal Drug Administration that a drug product's therapeutic equivalence evaluation has been changed from an A (therapeutically equivalent) category rating to any B category rating indicating therapeutic inequivalence or questionable equivalence, the Formulary Board may recommend to the ~~State Board of Health or the~~ Commissioner, pursuant to § 32.1-20, that the Formulary be summarily amended to delete the drug product simultaneously with the institution of proceedings for a public hearing. In acting on the Formulary Board's recommendations, the ~~State Board of Health~~ *Commissioner* need not conduct further proceedings under the Administrative Process Act.