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

In accordance with apparent legislative intent, this section as revised is broadened to address requirements of law with respect to any controlled dangerous substance, rather than merely with respect to marijuana and narcotics. This revision is called to the attention of the General Assembly.

4-223. NEW DRUGS.

(A) SCOPE OF SECTION.

THIS SECTION DOES NOT APPLY TO ANY DRUG THAT:

(1) WAS SOLD IN THIS STATE OR INTRODUCED INTO INTERSTATE COMMERCE AT ANY TIME BEFORE THE ENACTMENT OF THE FEDERAL ACT, IF ITS LABELING CONTAINED THE SAME REPRESENTATIONS CONCERNING THE CONDITIONS OF ITS USE; OR

(2) IS LICENSED UNDER THE PUBLIC HEALTH SERVICE ACT OF JULY 1, 1944 OR UNDER THE ANIMAL VIRUS-SERUM-TOXIN ACT OF MARCH 4, 1913.

(B) PROHIBITIONS.

A PERSON MAY NOT SELL, GIVE AWAY, OR DELIVER ANY NEW DRUG:

(1) UNLESS AN APPROVED APPLICATION FOR THE DRUG IS IN EFFECT UNDER § 355 OF THE FEDERAL ACT; OR

(2) UNLESS AN APPLICATION HAS BEEN APPROVED BY THE SECRETARY AND IS IN EFFECT UNDER THIS SECTION, IF THE DRUG IS NOT SUBJECT TO THE FEDERAL ACT.

(C) FILING OF APPLICATION WITH SECRETARY.

TO HAVE AN APPLICATION APPROVED BY THE SECRETARY, AN APPLICANT SHALL FILE WITH THE SECRETARY AN APPLICATION THAT SETS FORTH:

(1) FULL REPORTS OF THE INVESTIGATIONS THAT HAVE BEEN MADE TO SHOW WHETHER THE DRUG IS SAFE FOR USE AND WHETHER THE DRUG IS EFFECTIVE IN USE;

(2) A FULL STATEMENT OF THE COMPOSITION OF THE DRUG;

(3) A FULL DESCRIPTION OF THE METHODS USED IN, AND THE FACILITIES AND CONTROLS USED FOR, THE MANUFACTURE, PROCESSING, AND PACKING OF THE DRUG;