(I) THE NAME DESIGNATED UNDER THE FEDERAL ACT;

(II) IF A NAME HAS NOT BEEN DESIGNATED UNDER THE FEDERAL ACT, BUT THE DRUG OR INGREDIENT HAS BEEN RECOGNIZED IN AN OFFICIAL COMPENDIUM, THEN THE TITLE USED IN THE COMPENDIUM; OR

(III) IF A NAME CAN NOT BE DETERMINED UNDER ITEMS(I) OR(II) OF THIS PARAGRAPH, THE COMMON OR USUAL NAME OF THE DRUG OR INGREDIENT.

(2) IN APPLYING THE PROVISIONS OF PARAGRAPH (1)(II) OF THIS SUBSECTION, IF A DRUG OR AN INGREDIENT OF A DRUG IS RECOGNIZED IN BOTH THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY AND IN THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES UNDER DIFFERENT OFFICIAL TITLES, THE TITLE USED IN THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY IS THE ESTABLISHED NAME, UNLESS THE DRUG IS LABELED AND OFFERED FOR SALE AS A HOMEOPATHIC DRUG, IN WHICH EVENT THE OFFICIAL TITLE USED IN THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES IS THE ESTABLISHED NAME.

REVISOR'S NOTE: This subsection is new language derived without substantive change from former Article 43, § 189B(6).

(D) NEW DRUG.

"NEW DRUG" MEANS ANY DRUG THAT:

(1) AMONG EXPERTS QUALIFIED BY SCIENTIFIC TRAINING AND EXPERIENCE TO EVALUATE THE SAFETY AND EFFECTIVENESS OF DRUGS, IS NOT RECOGNIZED GENERALLY AS SAFE AND EFFECTIVE FOR USE UNDER THE CONDITIONS SPECIFIED, RECOMMENDED, OR SUGGESTED IN THE LABELING OF THE DRUG; OR

(2) AS A RESULT OF INVESTIGATIONS TO DETERMINE ITS SAFETY AND EFFECTIVENESS FOR USE, HAS BECOME RECOGNIZED BY THESE EXPERTS AS SAFE AND EFFECTIVE UNDER THE CONDITIONS, BUT THAT, OTHER THAN IN THE INVESTIGATIONS, HAS NOT BEEN USED TO A MATERIAL EXTENT OR FOR A MATERIAL TIME UNDER THE CONDITIONS.

REVISOR'S NOTE: This subsection is new language derived without substantive change from former Article 43, § 187A(r).

(E) PRESCRIPTION DRUG.

"PRESCRIPTION DRUG" MEANS A DRUG THAT, UNDER § 4-220 OF THIS SUBTITLE, MAY BE DISPENSED ONLY ON THE PRESCRIPTION OF A HEALTH PRACTITIONER WHO IS AUTHORIZED BY LAW TO PRESCRIBE THE DRUG.