REVISOR'S NOTE: This section is new language derived without substantive change from former Article 43, § 189D(a), (b), (c), (e)(1), (f), and (g).

In subsection (a) of this section, former Article 43, § 189D(3), which specified an exception to former § 189B, is deleted as unnecessary and potentially misleading. Every drug is subject to the provisions on misbranded drugs and, in any event, nothing in former Article 43, § 189D purported to have any effect on the provisions of former Article 43, § 189B.

In the introductory language of subsection (b) of this section, the former references to offering a drug for sale and holding a drug for sale are deleted as unnecessary in light of the rule of construction in § 4-102(a) of this title.

In subsection (c) of this section, the former reference to a list of "articles used as components of the drug" is deleted as unnecessary in light of the requirement of subsection (c)(2) of this section.

4-224. EXEMPTION OF NEW DRUGS INTENDED FOR INVESTIGATIONAL USE ONLY.

(A) APPLICATION OF SECTION.

(1) A NEW DRUG IS NOT SUBJECT TO THE REQUIREMENTS OF § 4-223 OF THIS SUBTITLE IF IT IS EXEMPTED BY A RULE OR REGULATION ADOPTED UNDER THIS SECTION.

(2) THIS SECTION DOES NOT REQUIRE ANY CLINICAL INVESTIGATOR TO SUBMIT DIRECTLY TO THE SECRETARY ANY REPORT ON THE INVESTIGATIONAL USE OF A DRUG.

(B) ADOPTION OF RULES AND REGULATIONS.

THE SECRETARY SHALL ADOPT RULES AND REGULATIONS TO EXEMPT FROM THE REQUIREMENTS OF § 4-223 OF THIS SUBTITLE ANY DRUG THAT IS INTENDED ONLY FOR INVESTIGATIONAL USE BY EXPERTS WHO ARE QUALIFIED BY SCIENTIFIC TRAINING AND EXPERIENCE TO INVESTIGATE THE SAFETY AND EFFECTIVENESS OF THE DRUG. IN ADDITION TO ANY OTHER CONDITIONS THAT MAY BE IMPOSED FOR THE PROTECTION OF THE PUBLIC HEALTH, THE RULES AND REGULATIONS MAY REQUIRE AS A CONDITION FOR THE EXEMPTION OF A DRUG THAT:

(1) BEFORE ANY CLINICAL TESTING OF A NEW DRUG IS UNDERTAKEN, THE MANUFACTURER OF THE DRUG OR THE SPONSOR OF THE INVESTIGATION OF THE DRUG SUBMIT TO THE SECRETARY REPORTS OF PRECLINICAL TESTS OF THE DRUG, INCLUDING TESTS ON ANIMALS, THAT ARE ADEQUATE TO JUSTIFY THE PROPOSED CLINICAL TESTING;