

As to subsection (d)(1) of this section, § 355(i) of the Federal Act provides that the Secretary of Health and Human Services shall adopt regulations to exempt from the federal requirements for new drugs any new drug that is intended only for investigational use and that otherwise meets the requirements of any regulation adopted under that section.

4-225. INSPECTION OF RECORDS REGARDING NEW DRUGS.

ANY PERSON WHO IS REQUIRED UNDER § 4-223 OR § 4-224 OF THIS SUBTITLE TO KEEP RECORDS AND ANY PERSON WHO IS IN CHARGE OR CUSTODY OF ANY OF THESE RECORDS, ON THE REQUEST OF THE SECRETARY, SHALL PERMIT THE SECRETARY TO HAVE ACCESS TO, COPY, AND VERIFY THE RECORDS AT ANY REASONABLE TIME.

REVISOR'S NOTE: This section is new language derived without substantive change from former Article 43, § 189D(e)(2).

4-226. PRINTED INFORMATION FOR USE OF PRACTITIONERS.

(A) IN GENERAL.

THE MANUFACTURER, PACKER, OR DISTRIBUTOR OF ANY PRESCRIPTION DRUG THAT IS SOLD OR DISTRIBUTED IN THIS STATE SHALL:

(1) KEEP CORRECT COPIES OF ANY PRINTED MATTER THAT IS:

(I) REQUIRED TO BE INCLUDED IN ANY PACKAGE IN WHICH THE DRUG IS SOLD OR DISTRIBUTED; OR

(II) APPROVED UNDER THE FEDERAL ACT; AND

(2) SEND COPIES OF THE PRINTED MATTER TO ANY HEALTH PRACTITIONER WHO IS AUTHORIZED TO ADMINISTER THE DRUG AND WHO MAKES A WRITTEN REQUEST FOR INFORMATION ABOUT THE DRUG.

(B) CONSTRUCTION OF SECTION.

THIS SECTION DOES NOT EXEMPT ANY PERSON FROM ANY LABELING REQUIREMENT IMPOSED UNDER ANY OTHER PROVISION OF THIS SUBTITLE.

REVISOR'S NOTE: This section is new language derived without substantive change from former Article 43, § 187B(14).

In subsection (a)(1) of this section, "sold" is substituted for "offered for sale" in light of