

As to subsection (c)(2) of this section, the exemption under former Article 43, § 189B(7) referred to "any requirement of clause 1 of this subsection". However, there was no "clause 1" in former § 189B(7). The appropriate scope of the exemption was determined by checking the provision of the Federal Act from which former Article 43, § 189B was derived. See 21 U.S.C. § 352(f). That provision uses a "(1)" where former Article 43, § 189B(7) used an "(a)", and, for consistency, the later reference in former Article 43, § 189B(7) to "clause (1)" should have been to "clause (a)". The apparent intent, in any event, was to make the reference to exemptions apply only to the requirement for directions in labeling and not the requirement for warnings. Subsection (c)(2) of this section is revised accordingly.

4-218. MISBRANDED DRUGS.

(A) "ANTIBIOTIC DRUG" DEFINED.

IN THIS SECTION "ANTIBIOTIC DRUG" MEANS ANY DRUG THAT:

- (1) IS INTENDED FOR USE BY A HUMAN BEING;
- (2) CONTAINS ANY QUANTITY OF A CHEMICAL SUBSTANCE OR THE CHEMICALLY SYNTHESIZED EQUIVALENT OF A CHEMICAL SUBSTANCE THAT IS PRODUCED BY MICROORGANISMS; AND
- (3) CAN INHIBIT OR DESTROY MICROORGANISMS IN DILUTE SOLUTION.

(B) IN GENERAL.

IN ADDITION TO ANY OTHER GROUND THAT MAY APPLY UNDER § 4-217 OR § 4-220 OF THIS SUBTITLE, A DRUG IS MISBRANDED IF:

- (1) IT IS FOR USE BY A HUMAN BEING AND CONTAINS ANY QUANTITY OF THE NARCOTIC OR HYPNOTIC SUBSTANCE ALPHA-EUCAINE, BARBITURIC ACID, BETA-EUCAINE, BROMAL, CANNABIS, CARBROMAL, CHLORAL, COCA LEAVES, COCAINE, CODEINE, HEROIN, MARIJUANA, MORPHINE, OPIUM, PARALDEHYDE, PEYOTE, SULPHONMETHANE, OR ANY CHEMICAL DERIVATIVE OF ANY OF THESE SUBSTANCES, WHICH DERIVATIVE, AFTER INVESTIGATION, HAS BEEN DESIGNATED AS HABIT FORMING UNDER A RULE OR REGULATION ADOPTED UNDER THE FEDERAL ACT OR BY THE SECRETARY UNDER THIS SUBTITLE, UNLESS ITS LABEL STATES THE NAME AND QUANTITY OR PROPORTION OF THE SUBSTANCE OR DERIVATIVE AND, IMMEDIATELY BESIDE THAT INFORMATION, A WARNING THAT STATES: "WARNING -- MAY BE HABIT FORMING.";