

(II) THE FORMULA OF THE DRUG SHOWING QUANTITATIVELY EACH INGREDIENT OF THE DRUG TO THE EXTENT REQUIRED FOR LABELS UNDER THE FEDERAL ACT; AND

(III) A BRIEF SUMMARY OF ANY OTHER INFORMATION THAT RELATES TO THE SIDE EFFECTS, CONTRAINDICATIONS, OR EFFECTIVENESS OF THE DRUG, AS IS REQUIRED BY THE RULES AND REGULATIONS ADOPTED UNDER THE FEDERAL ACT.

(C) APPLICATION OF REQUIREMENTS FOR DRUGS RECOGNIZED IN AN OFFICIAL COMPENDIUM.

(1) FOR PURPOSES OF SUBSECTION (B)(5) OF THIS SECTION, WHICH IMPOSES PACKAGING AND LABELING REQUIREMENTS ON ANY DRUG THAT IS PURPORTED TO BE RECOGNIZED IN AN OFFICIAL COMPENDIUM, THE PROVISIONS OF THIS SUBSECTION SHALL APPLY.

(2) (I) EXCEPT AS OTHERWISE PROVIDED IN THIS SUBSECTION, IF THE DRUG IS RECOGNIZED IN BOTH THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY AND IN THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES, IT IS SUBJECT TO THE PACKAGING AND LABELING REQUIREMENTS OF THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY.

(II) IF THE DRUG IS LABELED AND OFFERED FOR SALE AS A HOMEOPATHIC DRUG, IT IS SUBJECT TO THE PACKAGING AND LABELING REQUIREMENTS OF THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES AND NOT TO THE REQUIREMENTS OF THE UNITED STATES PHARMACOPOEIA AND NATIONAL FORMULARY.

(3) IF THERE IS AN INCONSISTENCY BETWEEN THE PROVISIONS OF PARAGRAPH (2) OF THIS SUBSECTION AND THE REQUIREMENTS OF SUBSECTION (B)(2), (3), OR (4) OF THIS SECTION AS TO THE NAME BY WHICH A DRUG OR ITS INGREDIENTS SHALL BE DESIGNATED, THE REQUIREMENTS OF SUBSECTION (B)(2), (3), OR (4) OF THIS SECTION CONTROL.

(D) RULES AND REGULATIONS ON MISBRANDED DRUGS.

(1) FOR PURPOSES OF SUBSECTION (B)(1) OF THIS SECTION, AFTER INVESTIGATION, THE SECRETARY MAY ADOPT A RULE OR REGULATION THAT DESIGNATES ANY CHEMICAL DERIVATIVE OF ANY SUBSTANCE NAMED IN THAT SUBSECTION AS HABIT FORMING.

(2) IF, AS TO A PARTICULAR DRUG, COMPLIANCE WITH ANY REQUIREMENT OF SUBSECTION (B)(3) OR (4) OF THIS SECTION IS IMPRACTICAL, THE SECRETARY SHALL ADOPT A RULE OR REGULATION THAT, TO THE EXTENT APPROPRIATE, EXEMPTS THE DRUG FROM THE PROVISIONS OF THOSE SUBSECTIONS.

(3) (I) IF THE SECRETARY FINDS THAT A DRUG IS LIABLE TO DETERIORATION, THE SECRETARY MAY ADOPT A RULE OR