7-LS0094\A

HOUSE BILL NO. 28

IN THE LEGISLATURE OF THE STATE OF ALASKA

SEVENTEENTH LEGISLATURE - FIRST SESSION

BY REPRESENTATIVE KOPONEN

Introduced: 1/21/91
Referred: Labor and Commerce, Health, Education and Social Services, Finance

A BILL

FOR AN ACT ENTITLED

"An Act relating to restrictions on the use of new and experimental drugs."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 17.20.110 is amended to read:

Sec. 17.20.110. SALE OF NEW DRUGS. A person may not sell, deliver, offer for sale, hold for sale or give away a new drug unless **it satisfies either of the following:**

(1) **it is a new drug, and a new drug application has been approved for it under 21 U.S.C. 355 and the approval has not been withdrawn, terminated, or suspended;** [AN APPLICATION FOR IT HAS BECOME EFFECTIVE UNDER THE FEDERAL ACT,] or

(2) [WHEN NOT SUBJECT TO THE FEDERAL ACT UNLESS THE DRUG HAS BEEN TESTED AND HAS NOT BEEN FOUND TO BE UNSAFE FOR USE UNDER THE CONDITIONS PRESCRIBED, RECOMMENDED, OR SUGGESTED IN THE LABELING OF IT, AND BEFORE SELLING OR OFFERING IT FOR SALE THERE HAS BEEN FILED WITH] the commissioner **has approved a new drug** [AN] application setting out

(A) full reports of investigations **that** [WHICH] have been made to show

whether or not the drug is safe for use **or whether the new drug is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug**;

(B) a full list of the articles used as components of the drug;

(C) a full statement of the composition of the drug;

(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

(E) samples of the drug and articles used as components of it **that** [WHICH] the commissioner requires; and

(F) specimens of the labeling proposed to be used for the drug.

*** Sec. 2.** AS 17.20 is amended by adding a new section to read:

Sec. 17.20.122. WITHDRAWAL OR SUSPENSION OF APPROVAL. (a) The commissioner shall issue an order withdrawing approval of an application concerning a new drug if, after giving written notice to the applicant and an opportunity for a hearing, the commissioner makes any of the following findings:

(1) that clinical or other experience, tests, or other scientific data show that the new drug is unsafe for use under the conditions of use upon the basis of which the application was approved;

(2) that new evidence of clinical experience, not contained in the application or not available to the department until after the application was approved, or tests by new methods, or tests by methods not considered reasonably applicable when the application was approved, evaluated together with the evidence available to the department when the application was approved, shows that the new drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved;

(3) on the basis of new information with respect to the new drug, evaluated together with the evidence available to the department when the application was approved, that there is a lack of substantial evidence that the new drug will have the effect it purports or is represented to have, under the conditions of use prescribed, recommended, or suggested in the labeling or advertising of the new drug;

(4) that the application contains an untrue statement of material fact;

(5) that the applicant has failed to establish a system for maintaining required

records, or has repeatedly or deliberately failed to maintain required records or to make required reports, or the applicant has refused to permit access to, or copying or verification of, required records;

(6) that on the basis of new information before the department, evaluated together with the evidence before it when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the new drug are inadequate to ensure and preserve its identity, strength, quality, purity, composition, and characteristics as determined by qualified experts selected by the department, and were not made adequate within a reasonable time after receipt of written notice from the department specifying the matter complained of;

(7) that on the basis of new information before it, evaluated together with the evidence before it when the application was approved, the labeling or advertisement of the new drug, based on an evaluation of all material facts, is false or misleading in any particular and is not corrected within a reasonable time after receipt of written notice from the department specifying the matter complained of.

(b) Upon a finding that there is an imminent hazard to the public health, the commissioner may suspend the approval for a new drug application immediately.

(c) An order under (a) or (b) of this section shall be revoked whenever the commissioner finds that the facts justify revocation.

*** Sec. 3.** AS 17.20.130 is amended to read:

Sec. 17.20.130. EXEMPTIONS. AS 17.20.110 does not apply to a drug

(1) intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs **if** [PROVIDED] the drug is plainly labeled "for investigational use only" **and is used under conditions that meet the requirements of regulations adopted by the department that are necessary to protect the public health;** or

(2) licensed under **either 21 U.S.C. 151 - 158 (**[THE] Virus, Serum, and Toxin Act**) or 42 U.S.C. 262 (Public Health Service Act)** [OF JULY 1, 1902 (U.S.C. 1934 ED. TITLE 42, CHAP. 4)].