SUBJECT: Definition of manufacture under the Food, Drug and Cosmetic Act

COMMITTEE: Public Health — committee substitute recommended

VOTE: 5 ayes — Berlanga, Hirschi, Davila, Glaze, Maxey

0 nays

4 absent — Coleman, Delisi, Janek, Rodriguez

WITNESSES: For — None

Against — None

On — Dennis E. Baker, Texas Department of Health

BACKGROUND: The Texas Food, Drug and Cosmetic Act is codified in Chapter 431 of the Health and Safety Code. The act defines "manufacture" as "the process of combining or purifying food and packaging food for sale to a consumer at wholesale or retail." The term "manufacture" and its variations are used throughout the act in provisions dealing with drugs, devices and cosmetics as well as in provisions dealing with food.

The commissioner of health may issue an emergency order relating to the manufacture of a food, drug, device or cosmetic under the jurisdiction of the Texas Department of Health (q2TDH) if the commissioner determines that the manufacture creates or poses an immediate and serious threat to human life or health and that other procedures for resolving or preventing the occurrence of the situation would result in unreasonable delay. In some circumstances, the emergency order may be issued without notice and hearing, but TDH must set a time and place for a later hearing to affirm, modify, or set aside the emergency order. The hearing must comply with TDH rules.

DIGEST: CSHB 492 would amend the Texas Food, Drug and Cosmetic Act by expanding the definition of "manufacture" to include:

- repackaging or otherwise changing the container, wrapper or labeling

of any food;

- the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing or quality control of a drug or drug product;
- the process of preparing, fabricating, assembling, processing, packing, repacking, labeling or relabeling a device; or
- making any cosmetic product by chemical, physical, biological or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

The term would not include distribution processes for alcoholic beverages if those process did not involve any of the other processes defined as a form of "manufacture."

CSHB 492 also would require that hearings on emergency orders be held under the contested case provisions of the Texas Administrative Procedure Act and the formal hearing rules of the Texas Board of Health.

The bill would take effect September 1, 1997.

SUPPORTERS SAY:

CSHB 492 would clarify confusing provisions of the Texas Food, Drug and Cosmetic Act. The current general definition of "manufacture" applies only to food; however, the term also is used and defined differently in sections addressing drugs, devices and cosmetics. CSHB 492 would make the general definition of "manufacture" comprehensive and user-friendly by delineating those actions that constitute manufacture of drugs, devices and cosmetics.

CSHB 492 also would clarify procedures in emergency orders by stipulating in statute that the mechanisms TDH currently uses to administer these hearings.

OPPONENTS SAY:

No apparent opposition.

NOTES:

The committee substitute amended the definition of "manufacture" to delete

the process of “holding” a drug or drug product and exempt the distribution of alcoholic beverages. The committee substitute also deleted provisions that would have added the sale of any adulterated or misbranded food, drug, device or cosmetic in Texas to the list of prohibited acts and allowed certain inspection of establishments where cosmetics were manufactured.