FDA Urges No Change in Reserpine; Will Lower Some Tolerances for PCB

No changes should be made in either the labeling or the marketing of the drug reserpine, an advisory panel of the Food & Drug Administration has concluded. The panel's recommendations received the unanimous support of its members.

National Cancer Institute findings on reserpine had suggested that the drug, used against high blood pressure, might be carcinogenic. The suggestion came from studies of the drug administered to rodents.

According to the FDA panel, however, the animal data had not been adequately analyzed in order to reach such a conclusion linking the medication to a cancer risk. Moreover, Ciba-Geigy Corporation, manufacturer of reserpine, has also challenged the pathologists' review of the animal data as to its adequacy.

In addition, the panel did not see strong evidence in the epidemiological data that *would establish a link between reserpine* usage and breast cancer.

FDA also said last week that it was lowering the tolerances for polychlorinated biphenyls in fish, poultry and dairy products. The agency said that new evidence indicates that POB's are more toxic than previously thought.

In particular, recent studies have linked *the chemicals to liver tumors and reproductive problems in test animals*, FDA said.

The impact of FDA's action is expected to fall particularly hard on commercial fishing interests. The agency notes that it has estimated that the new tolerances could result in a loss of $6 million worth of fish a year, virtually all freshwater species.

Details of the changes in the tolerances appear in the June 29 *Federal Register*. The new tolerances, which are in the low parts-per-million range, are to become effective on products shipped in interstate commerce on August 28.