HEXACHLOROPHENE IN DRUGS, SOAPS, AND COSMETICS

Hexachlorophene is widely used as an antibacterial component in a large number of products such as lotions, ointments, powders, soaps, shampoos and deodorants. It is used in such products because of its bacteriostatic action against gram-positive organisms, especially staphylococcus strains. It offers no protection against gram-negative infections, and its antibacterial activity depends on repeated use.

Hexachlorophene is readily absorbed into the blood stream from normal skin, including that of newborns, and especially from abraded and burned skin. The toxicity of hexachlorophene appears to be related to its concentration in the blood, and this concentration increases with the amount of exposure to hexachlorophene. The margin of safety between toxic and nontoxic blood levels in humans and animals appears to be narrow.

In a recent study, baby monkeys developed brain edema when bathed daily for 90 days with 3% hexachlorophene. *Misuse* of hexachlorophene products in humans such as application on burn surfaces or use in vaginal packs, has resulted in central nervous system toxicity and death.

Daily human use of lower concentrations of hexachlorophene in deodorant soaps or hand scrubs, which may produce chronic blood levels of approximately 1.5 mcg/ml, is not known to produce toxicity, even after long-term use.

In the past two decades there has been a rapidly expanding use of hexachlorophene. To protect consumers from any potential hazard resulting from such increased exposure to hexachlorophene, FDA has proposed new action to limit its inclusion n drugs and related products. The Agency also has acted to ensure that in the future all antibacterial agents intended for chronic daily use have been adequately evaluated for safety and efficacy. A summary of FDA proposed action follows:

1. Hexachlorophene may not be used in cosmetic products, except as a preservative in levels up to 0.1%, and then only when other suitable preservatives are not available.
2. When hexachlorophene is a component of drugs which have approved new drug applications, the drug label must read "Caution: Contains Hexachlorophene. For external washing only. Rinse thoroughly." The hexachlorophene level may not exceed .75%.
3. Drugs containing hexachlorophene in levels over .75% must bear the prescription label.
4. A panel of experts is being consulted to determine the safety, efficacy and appropriate labeling of all over-the-counter drugs — such as bar soaps — offered for routine, daily use as antibacterial agents.

The proposed action in no way restricts physician-directed use of hexachlorophene products, including the use of 3% hexachlorophene as a surgical or disinfectant scrub. The action does, however, reflect FDA concern that there should be medical justification for the addition of antibacterial agents to readily available consumer products.

The new proposals cited above supplement an FDA warning against total body bathing of infants and adults with products containing HCP in 2% and 3% concentrations (see FDA Drug Bulletin dated December 1971).

Comments on the FDA proposals should be sent prior to March 7, 1972, to the Hearing Clerk, Department of HEW, Room 6-88, 5600 Fishers Lane, Rockville, Maryland 20852.

CORONARY VASODILATOR EFFICACY

Long-acting coronary "vasodilators," widely-prescribed in the management of angina pectoris, will require extensive study as a result of a National Academy of Sciences/National Research Council report questioning the quality of evidence on the drugs' effectiveness.

The NAS/NRC panel, after evaluating all available evidence about the drugs, concluded:

- Isosorbide dinitrate tablets, when administered by the *sublingual* route, are "probably" effective for the treatment of attacks of angina pectoris and for prophylaxis in situations likely to provoke such attacks.
- The same drug, isosorbide dinitrate tablets, is only "possibly" effective for the same indications when administered *orally* (swallowed).