

FOR FURTHER INFORMATION CON-

G. D. Schmidt, Division of Compliance,
Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 201-443-3426.

Dated: March 11, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

(FR Doc. 77-7803 Filed 3-17-77; 8:45 am)

[Doc. No. 76N-0020]

DRUG PRODUCT CONTAINING URETHAN
Withdrawal of Approval of Pertinent Part of
a New Drug Application

The Food and Drug Administration is withdrawing approval of Profenil Injection, effective March 28, 1977.

In a notice (Docket No. 76N-0020) published in the FEDERAL REGISTER of February 27, 1976 (41 FR 3523), the Director of the Bureau of Drugs offered an opportunity for hearing on his proposal to issue an order withdrawing approval of the following drug product:

NDA 5-695; that part of the NDA pertaining to Profenil Injection, containing alverine hydrochloride as the active ingredient and urethan as an inactive ingredient. The product is no longer marketed. The NDA holder is Chemical Management Services, Division of Chemetron Corp., 111 E. Wacker Dr., Chicago, IL 60601.

The basis of the proposed action was that the drug product has not been shown to be safe for use because of the carcinogenic nature of urethan, which is one of the product's inactive components.

All drug products that contain urethan as either an active or an inactive ingredient or that contain an ingredient related or similar to urethan are subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857.

Neither the holder of the application nor any other person filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes election by such persons not to avail themselves of the opportunity for hearing.

The Director of the Bureau of Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)) and under authority delegated to him (21 CFR 5.31) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), finds that tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that neither the drug product nor its inactive component urethan is shown to be safe for

use under the conditions of use on the basis of which the application was approved.

Therefore, pursuant to the foregoing finding, approval of that part of new drug application no. 5-695 pertaining to Profenil Injection, and all amendments and supplements applying thereto, is withdrawn effective March 28, 1977.

Shipment in interstate commerce of the above product or of any drug product that contains urethan as either an active or an inactive ingredient or that contains an ingredient related or similar to urethan (21 CFR 310.6), not the subject of an approved new drug application, will then be unlawful.

Dated: March 4, 1977.

J. RICHARD CROFT,
Director, Bureau of Drugs.

(FR Doc. 77-2824 Filed 3-11-77; 8:58 am)