

**DRUG PRODUCTS CONTAINING DIPYRONE**  
**Withdrawal of Approval of New Drug Applications**

**AGENCY:** Food and Drug Administration  
**ACTION:** Notice.

**SUMMARY:** This notice withdraws approval of the new drug applications (NDAs) for drug products containing dipyrone. The drug products have been

found to reduce fever, but they are not shown to be safe for use.

**DATE:** Effective June 27, 1977.

**ADDRESS:** Requests for opinion of the applicability of this notice to a specific product should be directed to the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Ronald L. Wilson, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, (301-443-3650).

**SUPPLEMENTARY INFORMATION:** In this notice (FDA Docket No. 76N-0311) published in the FEDERAL REGISTER of September 3, 1976 (41 FR 37386), the Director of the Bureau of Drugs offered an opportunity for a hearing on a proposal to issue an order withdrawing approval of the NDAs for the drug products described below. The basis of the proposed action was that the drugs are not shown to be safe for use.

NDA No.	Drug name	Firm name
16-124	Narone (dipyrone) tablets	Ulmor Pharmacal Co., 1400 Harmon Pl., Minneapolis, Minn. 55402.
16-122	Pyrazin (dipyrone)	Savage Laboratories, Inc., P.O. Box 1000, Missouri City, Tex. 77550.
16-127	Pyrazin (dipyrone) injection	H. E. Maury Biological Co., Inc., 5100 South Western Ave., Los Angeles, Calif. 90047.
16-122	do	Savage Laboratories, Inc.
16-125	Pyrazin (dipyrone) tablets	Do.
16-123	do	Do.
16-128	Dimethane (dipyrone) injection	Phillips Roxanne Laboratories, Inc., Division Phillips Roxanne, Inc., 221 Oak St., Columbus, Ohio 43216.
16-125	Dimethane (dipyrone) tablets	Do.
16-123	Protomp (dipyrone) tablets	Tablet Rock Laboratories, Inc., P.O. Box 1063, Greenville, S.C. 29602.
16-129	Protomp (dipyrone) pediatric	Do.
16-124	Protomp (dipyrone) oral liquid	Do.
16-129	Novadon (dipyrone) tablets	Winthrop Laboratories, 90 Park Ave., New York, N.Y. 10016.
16-126	Novadon (dipyrone) injection	Do.
16-124	do	Gottman Pharmaceutical Co., Inc., 1810 McDonald Ave., Brooklyn, N.Y. 11223.
16-127	do	Myers-Carter Laboratories, Inc., subsidiary of Chromalloy American Corp., 5160 West Bethany Home Rd., Glendale, Ariz. 85001.
16-128	do	USV Pharmaceuticals Corp., 1 Scarsdale Rd., Tuckahoe, N.Y. 10707.
16-125	Narone (dipyrone) injection	Ulmor Pharmacal Co.

All drug products that are identical, related, or similar to a drug product named above, not the subject of an approved new drug application, are covered by the NDA's reviewed and are subject to this notice (as specified in 21 CFR 310.5). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, at the address given above.

In response to the September 3, 1976 notice, two firms submitted requests for hearing and requests for an extension of time to file supporting data. The Food and Drug Administration denied both requests for an extension of time. One of the firms later withdrew its request for hearing. The other, Savage Laboratories, elected not to submit the supporting data and analyses that are required by 21 CFR 314.200 and, therefore, its request for hearing is denied.

No 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 a hearing.

Winthrop Products, though not electing to request a hearing for its products, did request an extension of time to file a hearing request and submitted a published study to demonstrate the safety of dipyrone. The request for an extension of time was denied, and the study was reviewed and found not to be relevant to the safety issue on the basis of which the drug products containing dipyrone are being withdrawn.

On the basis of new evidence, not contained in the applications or not available until after the applications were approved, evaluated together with the evidence available when the applications were approved, the Commissioner of Food and Drugs finds that such drugs have not been shown to be safe for use upon the basis of which the applications were approved. Furthermore, he has determined that Savage Laboratories has failed to meet the requirements of 21 CFR 314.200 by not submitting data and analyses in support of its hearing request

showing there is a genuine and substantial issue of fact requiring a hearing.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended (21 U.S.C. 355(e)) and under authority delegated to the Commissioner (21 CFR 5.1), the request for a hearing is denied, and approval of the NDA's providing for the drug products named above, and all amendments and supplements applying thereto, is withdrawn effective June 27, 1977.

Shipment in interstate commerce of the above-listed products or of any identical, related, or similar product, not the subject of an approved NDA, will then be unlawful.

Dated: June 7, 1977.

SHERWIN GARDNER,  
Acting Commissioner of  
Food and Drugs.

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