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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

(Docket No. FDC-D-134; NDA 11-823)

G. D. SEARLE & CO.

Mornidine (Pipamazine) Tablets and Injection; Notice of Withdrawal of Approval of New-Drug Application

G. D. Searle & Co., Post Office Box 5110, Chicago, Ill. 60680, holder of effective new-drug application No. 11-823 for the

drug pipamazine, marketed as Mornidine Tablets (5 milligrams per tablet) and Mornidine Injection (5 milligrams per milliliter), has requested withdrawal of approval of said application.

This application became effective July 22, 1959. The labeling recommended the drug for all conditions in which it is desirable to stop nausea and vomiting, including the nausea and emesis of pregnancy, surgery, radiotherapy, nitrogen mustard therapy, and gastroenteritis.

A supplement to expand the section on clinical applications submitted in April 1962 was ruled incomplete in June 1962.

The medical data in the new-drug application were completely reviewed, evaluated, and summarized in September 1963, and it was concluded that (1) there was inadequate scientific evidence to show efficacy for any of the labeled indications and (2) there was inadequate evidence that the drug is safe for use in pregnant women.

On June 21, 1963, the applicant submitted reports on abortion, miscarriage, and fetal mortality. The data were inconclusive, but the applicant proposed labeling revisions in December 1963 to note that animal reproductive studies were underway and to state that the effect on the fetus was not known.

The applicant was notified June 3, 1964, that the supplement to the application was incomplete in that: (1) The safety of Mornidine (pipamazine) in the specific condition of nausea and vomiting of pregnancy was not substantiated; (2) the safety of intravenous administration was not substantiated; (3) the labeling failed to warn against the asso-

ciation of pernicious vomiting of pregnancy with serious hepatic lesions and possibly dangerous synergistic effect of a phenothiazine drug in this situation; and (4) the labeling did not adequately emphasize the danger of oversedation. The applicant was further advised to insert a pregnancy warning statement in the labeling and that effective October 10, 1964, the application would be reviewed again from the standpoint of efficacy.

The firm advised the Food and Drug Administration on September 21, 1964, and April 14, 1966, that it had discontinued manufacture and supply of Mornidine Tablets and Ampuls. The product was not recalled at that time and several years later stocks were found in pharmacies.

On February 4, 1969, the Food and Drug Administration notified the applicant of its intention to initiate proceedings to withdraw approval of the application. On February 10, 1969, G. D. Searle & Co. stated that both Mornidine Tablets and Injection were being recalled to the retail level, requested withdrawal of approval of the application, and waived opportunity for a hearing in this regard, further saying that "the data presented to the Food and Drug Administration prior to the marketing of Mornidine in 1959 might be lacking in substantial evidence of safety and effectiveness as might now be required by the Drug Amendments of 1962."

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under the authority delegated to him (21 CFR 2.120), finds on the basis of new information evaluated with evidence available when the application was approved that the drug is not shown to be safe and effective for use under the conditions of use upon which the application was approved.

Therefore, pursuant to the foregoing finding, approval of new-drug application No. 11-823 and all amendments and supplements thereto applying to Mornidine Tablets and Injection is withdrawn, effective on the date of signature of this document.

Dated: July 10, 1969.

HERBERT L. LEV, JR.  
Commissioner of Food and Drugs.