ORIGIN/ACTION

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OSD	USIA	NSA

DEPARTMENT OF STATE

81 A·IRGRAM

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FOR RM USE ONLY

A-116, NO.

UNCLASSIFIED

HANDLING INDICATOR

TO : AmEmbasy RIO DE JANEIRO

Nov 17 10 44 AM '64

FROM : DEPARTMENT OF STATE DATE:

SUBJECT : Drug Recall: Telmid (Dithiazanine Iodide)

REF : Embassy's A-357, October 16, 1964

FROM THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The following information on drug products containing "diathiazine iodide" has been furnished by the Food and Drug Administration for transmittal to Dr. Costa.

Telmid is a trade name for dithiazanine iodide. The translation of Dr. Costa's letter referred to this compound as an "anti-heminitic" agent; however it is actually an anthelmintic.

Dithiazanine iodide has been marketed in the United States since 1958 by Eli Lilly and Company under the proprietary name Delvex. It is limited to prescription use. As a result of reports of adverse reactions and some deaths, revisions in labeling have been made on more than one occasion to restrict indications for use and to include additional precautionary statements.

In August 1964 the firm sent a letter to physicians prepared in collaboration with the Food and Drug Administration accompanied by the latest revision of labeling.

The letter included the following information:

"Eight deaths have been associated with the use of dithiazanine iodide in the past four years. In some cases deaths have occurred with as little as 100 mg. of the drug. Although the precise mechanism of these deaths is unknown they were preceded by gastro-intestinal symptoms, severe acidosis and shock.

Delvex should be

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FORM 4-62 DS-323

FOR DEPT. USE ONLY ☐ In ☒ Out

Drafted by: DHEW:OS:GGates:mac (11-13-64)

Contents and Classification Approved by: OPR:RM:JPBurke - 11/17/64

Clearances:

FDA - J. L. Harvey (memo)

SCI - Dr. H. I. Chinn (substance)

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Delvex should be reserved for the treatment of heavy and clinically significant strongyloidiasis or trichuriasis and for mixed infections in which either of these organisms is present. It is the only orally effective remedy now available for the treatment of strongyloidiasis and trichuriasis. Delvex should not be considered for use in carriers or mildly symptomatic patients with either or both of these two parasites.

Patients receiving Delvex should be followed closely. Therapy with the drug should be discontinued if there is a bluish-green color in the urine or a similar staining of the sclera. Complete information is included in the accompanying revised literature."

The labeling points out that in all six cases inwhich an autopsy was performed there was a diffuse bluish-green staining of most of the organs which is indicative of absorption. In a few patients, however, absorption of the drug has been manifested by blue discoloration of the skin and sclera without sequelae.

Dithiazanine iodide has not been removed from the market in the United States.

The Food and Drug Administration appreciates the cooperation of the Brazilian Ministry of Health in reporting adverse drug reactions and drug recalls in Brazil.

RUSK

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