

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

TO : ALL REGIONAL FOOD AND DRUG DIRECTORS  
ALL DISTRICT DIRECTORS  
ATTN: NAS/NRC COORDINATORS  
COMPLIANCE BRANCH CHIEFS

DATE: APR 3 1980  
DLC-Rx Drug Study  
Bulletin #242

FROM : CHIEF  
PRESCRIPTION DRUG COMPLIANCE BRANCH, HFD-313

SUBJECT: Class Action Followup  
Re: Potassium Arsenite Solution (Fowler's Solution)

## PURPOSE:

To advise the districts of the implementation of the referenced class action and to identify those firms marketing the subject product with indications for drug usage. This drug has not been evaluated under the Drug Efficacy Study Implementation (DESI) program and action will include any product which is not the subject of an approved New Drug Application (NDA).

## BACKGROUND AND DISCUSSION:

Fowler's Solution is a pre-1938 drug with its most recent compendial reference being NF X (1955) listing its indication - antileukemic. Fowler's Solution has never been the subject of a new drug application. We were advised by the Division of Oncology and Radiopharmaceutical Drug Products that Fowler's Solution no longer has a place in the market as an antileukemic. It was stated that, "It has not been shown effective in the treatment of leukemia in adequate and well-controlled studies" and that the "continued availability of the drug tends only to distract physicians from more effective therapy now available to the detriment of their patients." Additionally, the drug is toxic and may be highly carcinogenic under such intended use.

In view of the foregoing, we propose to initiate a DESI-type class action utilizing established DESI procedures to remove from the marketplace Fowler's Solution when indicated for use as an antileukemic and/or other unapproved indications not the subject of an approved New Drug Application (NDA) or investigational (IND) exemption.

We have identified the following two manufacturers who are marketing this drug for use as an antileukemic:

Humco Laboratories - Texarkana, Texas  
J.A. Borneman & Sons - Norwood, Pennsylvania

These two firms have been issued Regulatory Letters by HFD-310 in

accordance with established procedures. In order for this to be an effective class action, it is necessary that we also identify all such manufacturers of the product regardless of labeled drug indications for use. Regulatory Letters will issue from HFD-310 for all such products identified by the field via submission of an FD-3033 including a copy of the product's labeling. We will provide the District with a copy of any Regulatory Letter issued under this Bulletin as well as any response received as a result of the Regulatory Letter.

A copy of the Regulatory Letter issued to the firms known to be marketing Fowler's Solution is being supplied to the home districts and a copy of the form letter is being furnished to the other districts for information.

  
ALBERT LAVENDER

National Coordinator: Donald L. Leggett  
FTS: 8/443-4206

Enclosure

PRIORITY: HIGH  
PAC: 52002  
PRODUCT CODE:  
ESTIMATED TIME: 6 HOURS  
DUE DATE: APRIL 30, 1980

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