DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 15 1997

TRANSMITTED BY FACSIMILE

David L. Moore, R.Ph.
Manager, Professional Services
Schein Pharmaceutical, Inc.
620 N. 51st Ave.
Phoenix, AZ 85043

Re: NDA 17-441
InFed (iron dextran injection)
MACMIS ID#4474

Dear Mr. Moore:

This letter concerns promotional materials for Schein Pharmaceutical's InFed (iron dextran injection). Based on materials the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed as part of its ongoing monitoring program, it appears that Schein is promoting InFed for unapproved uses and making false or misleading promotional claims. These promotional activities are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder.

Specifically, Schein is promoting the use of InFed for use in"documented iron-deficiency anemia not amenable to oral therapy." However, InFed is indicated for the "treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible." The approved indication is more narrow than the expanded recommendation presented in Schein's promotional materials for InFed. Therefore, Schein is recommending the use of InFed in unapproved uses where the drug has not demonstrated to be safe and effective.

Schein also claims that InFed is "iron fast and [a]bout 40 percent of iron from IV iron dextran was bound to transferrin 11 hours after IV administration." These claims may be false and/or misleading. The reference cited for substantiation of this claim is based upon an article published by Kanakakorn et al. in the British Journal of Haematology, 1973. However, the method of measurement for serum iron and saturated and unsaturated transferrin in that article has been replaced by newer and better methods in the succeeding 23 years. Thus, these claims may be misleading and should be re-evaluated using current methods.

Schein should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter. Schein should submit a written response to DDMAC on or before January 31, 1996, describing the steps taken to ensure that the use of these materials have been discontinued.

Schein should direct its response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD, 20857. DDMAC reminds Schein that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #4474, in addition to the NDA number.

Sincerely,

Stephen W. Sherman

Stephen W. Sherman, MBA
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

infed.1397

draft: SSherman 1/3/97
comment: TAcher 1/6/97
comment: TAbrams 1/13/97
revised: SSherman 1/14/97
concur: TAbrams 1/14/97

cc:
HFD-40/NDA 17-441
HFD-40/chron/sherman/abrams
HFD-550/Fredd

MACMIS type code: lett
MACMIS content code: viol

MACMIS File ID #4474

Due date: January 31, 1997

close-out: no

FOI Status: **RELEASEABLE**