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JUL 14 1998

**TRANSMITTED BY FACSIMILE**

William-R. McIntyre, Ph.D.  
Vice President, Regulatory and Professional Affairs  
Schein Pharmaceutical, Inc.  
620 N. 51st Ave.  
Phoenix, AZ 85043

Re: Investigational New Drug for Iron Therapy  
MACMIS ID#6656

Dear Dr. McIntyre:

This letter concerns promotional materials for Schein Pharmaceutical's injectable iron therapy investigational new drug. Based on materials the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed as part of its ongoing monitoring program. DDMAC has concluded that Schein is promoting this investigational new drug prior to its clearance for marketing. These promotional activities are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder.

Specifically, Schein has disseminated a promotional advertisement that states "[a]n injectable iron therapy in a class of its own." This advertisement makes representations about a specific product. Thus, Schein is making representations in a promotional context that its investigational new drug is safe and effective for the purposes for which it is under investigation. Thus, these representations constitute pre-approval promotion and are in violation of the Act.

Schein should immediately suspend all promotional activities and materials that convey or contain the violative claims or information identified in this letter. Schein should submit a written response to DDMAC on or before July 29, 1998, 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

Dr. William R. McIntyre, Ph.D.  
Schein Pharmaceutical, Inc.

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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 #6656, in addition to the NDA number.

Sincerely,

A handwritten signature in black ink, appearing to be the initials 'SWS' or similar, enclosed in a slanted rectangular box.

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