CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76-019

APPROVAL LETTER

ANDA 76-019

MAR 17 2004

Abbott Laboratories
Hospital Products Division
Attention: Jonathan Dohnalek
200 Abbott Park Road, D-389, Bldg. J45/2
Abbott Park, IL 60064-6133

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Deferoxamine Mesylate for Injection USP, 500 mg/vial and 2 g/vial.

Reference is also made to your amendments dated October 30, 2003; and January 7, and February 5, 2004.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Deferoxamine Mesylate for Injection USP, 500 mg/vial and 2 g/vial, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Desferal® for Injection USP, 500 mg/vial and 2 g/vial, respectively, of Novartis Pharmaceuticals Corp.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all

proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert Lewis for
3/17/2004

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research