caused to be issued by the manufacturer, packer, or distributor of the drug, failed to include

(A) a true statement of information in brief summary relating to the effectiveness of said drug as required by regulation 21 CFR 1.105(e) in that the advertisement lacks fair balance in its presentation and does not fairly show the effectiveness of the drug in the conditions for which it is recommended or suggested in the advertisement since the advertisement represents,

(1) That therapy may be initiated parentally and then followed through orally without switching to another antibiotic but fails at this point to refer to the sensitivity study requirement contained in the labeling accepted under the certification requirements for the drug that " . . . in vitro sensitivity studies should be performed before Lincocin is utilized as sole antibiotic therapy;"

(2) That reactions are rare, even for patients sensitive to penicillin—does not share antigenicity with the penicillin group of compounds, "which representation is misleading, and fails at this point to refer to the "adverse experience" information contained in the labeling accepted under the certification requirements for the drug that "A few cases of hypersensitivity reactions such as angioneurotic edema, serum sickness and anaphylaxis have been reported;"

(3) That there are "no serious renal or neurologic abnormalities, no ototoxicity" and "no tooth discoloration to date" which representations are misleading in that the audience for whom the advertisement is intended is not advised at this point or with equal prominence or in reasonably close association with this information the facts that hematologic toxicity, manifested by neutropenia or leukopenia can occur and that the frequency of severe diarrhea is a unique feature of Lincocin therapy.

(B) a true statement of information in brief summary concerning those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and any other use or uses for which the dosage form advertised is commonly prescribed as required by regulation 21 CFR 1.105(g) in that the advertisement failed to include the following information from the labeling covered by the certification, or the applicable certification regulations (21 CFR 148.3 and 148X):

(1) The precautionary information that "With B-hemolytic streptococcal infections, treatment should continue for at least 10 days to diminish the likelihood of subsequent rheumatic fever or glomerulonephritis:"

(2) The side effect information which specifies the serious nature of the cases of hypersensitivity reactions, i.e., . . . "Angioneurotic edema, serum sickness and anaphylaxis" and fails to identify the usual agents which should be available for emergency treatment, i.e., "antihistamines, pressor amines, corticosteroids;"

(3) The precautionary information that ". . . in vitro sensitivity studies should be performed before Lincocin is utilized as sole antibiotic therapy."

(4) The statement "Other adverse reactions observed in a small proportion of patients . . ." appearing in the labeling is not included and is misleadingly changed in the advertisement to read "Side effects of small proportion . . ."

The aforesaid article misbranded when introduced into and while in interstate commerce, is subject to seizure and condemnation under 21 U.S.C. 334. Immediate seizure is requested. Please advise the action taken.

Very truly yours,

WILLIAM W. GOODRICH,
Assistant General Counsel, Food and Drug Division.