

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 80-515

Approval Letter

ND 80-515
AF 32-080

OCT 20 1971

Elkins-Sims, Inc.
Attention: Mr. Davis R. Reese
2 Eastbrook Lane
Cherry Hill, New Jersey 08034

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 305(b) of the Federal Food, Drug, and Cosmetic Act for Cyanocobalamin Injection, 100 mcg./ml. and 1000 mcg./ml.

Reference is also made to your communication dated September 23, 1971, enclosing manufacturing information and printed labeling for Elkins-Sims as a distributor.

Reference is also made to our communication dated September 21, 1971, stating that labeling revisions will be required within 60 days of receipt of Administration guidelines.

We have completed the review of this abbreviated new drug 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 periodic reporting requirements of Section 130.13(b)(4) of the new drug regulations are waived in regard to this application as published in the Federal Register of June 10, 1971.

Any significant change in the conditions outlined in this abbreviated new drug application, requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 130.9 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

It is noted that you intend to submit NDC and distributor's labeling when it becomes available. We will comment on this labeling when it is received.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

HSI

Henry E. Simmons, M.D., M.P.H.
Director
Bureau of Drugs

Enclosures

cc:
NYK-BO

Dup
BD-69
BD-67
BD-100
BD-22
BD-242
MAClark/JLMeyer/RJWolters 10-6-71
R/D init. by MAClark/JLMeyer 10-7-71
Final typing/wlb/10-7-71
Approved

*R. J. Walters
10 7-71
J. Meyer 10/8/71
M. Clark MD 10/10/71
J. W. [Signature] 10/12/71
J. [Signature] 10/12/71*