CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 80-515

ADMINISTRATIVE DOCUMENTS

# REVIEW OF ANDA

DATE COMPLETED: 8-2-71

ANDA #: 80-515

F.R. Date: 6-10-71

(Co. Name): Elkins-Sinn, Inc.
2 Easterbrook Lane
Cherry Hill, N.J. 08034

NAME OF DRUG:

Trade & Generic:

Cyanocobalomin Injection USP 30 mcg/cc
100 mcg/cc
1000 mcg/cc

Cyanocobalomin Injection USP 1000 mcg/cc with Gelatine

DATE OF SUBMISSION: 7-1 -71

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:

None submitted

2. Review of Labeling:

Immediate Container Labels

100 mcg/ml--10 ml vial
100 mcg/ml--30 ml vial
1000 mcg/ml--10 ml vial
1000 mcg/ml--30 ml vial

1. Delete indications and dosage sections (dosage in specific indications may be complex)
2. Add control number

This applies to these 4 forms

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DPSC Multiple dose vial label 30 mcg./cc

Immediate container label--Delete indications section. Add, "Protect from light"
Delete usual dosage range

DPSC Carton label--Delete indications section. Add, "Protect from light"
Delete usual dosage range

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Distributors multiple dose vial label--Immediate container label

100 mcg/ml--10 ml vial
100 mcg/ml--30 ml vial
100 mcg/ml-- 5 ml vial
1000 mcg/ml--10 ml vial
1000 mcg/ml--30 ml vial
1000 mcg/ml-100 ml vial

1. Delete indications and dosage sections
2. Add control number

This applies to all 6 forms

All "neutral" labels to bear company name. Distributors labels to be sent separately for evaluation when available.

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1 ml vial, 1000 mcg/ml — Immediate container label satisfactory
1 ml ampule, 1000 mcg/ml — Same as above
1 ml dosette syring, 1000 mcg/ml — Immediate container label satisfactory
1 ml dosette syring, 100 mcg/ml — Same as above
Box labels for above ampules, vials and syringes --- satisfactory

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ESI 10 ml or 30 ml 1000 mcg/ml--Immediate container label

1. Delete indications and dosage sections
2. Add control number

No provision is made for repository gel - See FR statement of 6-10-71

Distributors 10 ml or 30 ml multiple dose vial - Immediate Container label

1. Delete indications and dosage sections
2. Add control number

Insert: Requires revision to bring it into conformity with current Administration guidelines and published FR statement.

Conclusion: All labeling requires revisions to bring them into conformity with Administration guidelines.

RECOMMENDATIONS: Company to be so advised and copy of current guidelines to be supplied as soon as available.

/S/

A. S. Werner, M.D.,

| MEMO RECORD | AVOID ERRORS PUT IT IN WRITING | DATE Sept. 16, 1971 |
|---|---|---|
| Meeting between Dr. Marion Finkel and | | OFFICE DESI |
| TO: Dr. Margaret Clark | | DIVISION |

SUBJECT: Possible approval of 80-515

SUMMARY

Elkins-Sinn requested action on their ANDA submission for cyanocobalamin so that they might bid on a defense contract. Dr. Finkel was asked if it would be permissible to approve the submission with the label submitted by the firm. FDA labeling guidelines have not as yet been put in final form. Such an approval would be with the stipulation that the firm agree to relabel the drug within 60 days of an FDA request to do so. There are no substantive errors in the submitted label. Dr. Finkel agreed that such a course of action is acceptable.

SIGNATURE /S/

DOCUMENT NUMBER 80-515

FORM FDH-2034 (11/66)

REVIEW OF RESUBMISSION

DAT E COMPLETED: 10/6/71

ANDA#: 80-515

F.R. Date: 6/10/71
Elkins-Sinn, Inc.
2 Easterbrook Lane
Cherry Hill, N.J. 08034

NAME OF DRUG: Trade & Generic: Cyanocobalamin, U.S.P., 100 mcg/cc & 1000mcg/cc

DATE OF SUBMISSION: September 23, 1971

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

The firm submits final printed labels and labeling for the Elkins-Sinn labeling for the 100 mcg/cc and 1000 mcg/cc dosage forms. All other labeling for distributors and DPSC, including the 30 mcg/cc dosage form will be submitted at a later date. The firm is requesting action on their name labeling only.

Review of Labeling:

1. Container labels: Elkins-Sinn labels for 10 ml and 30 ml of both 100 mcg/cc and 1000 mcg/cc are satisfactory. Screen prints for vial labels submitted 7/1/71 are satisfactory.
2. Package Insert: The Elkins-Sinn final printed label is identical to the draft labeling, and is satisfactory. In our letter of 9/21/71 the firm was told that a possible revision of this labeling would be required when Administration guidelines are prepared for this product. The firm has agreed to this stipulation in their letter of 9/23/71.

CONCLUSION: The Elkins-Sinn labels provide for the safe and effective use of this product. Action on distributor labels deferred pending submission of such labeling. There is no bioavailability requirement for this product.

RECOMMENDATION: ANDA is medically approvable (with provisoes stated above).

/S/

Margaret A. Clark, M.D.

cc: Dup., BD-100, BD-69.
MAClark/mc/10/6/71

| MEMO RECORD | AVOID ERRORS PUT IT IN WRITING | DATE |
|---|---|---|
| FROM: H. T. Behrens | | OFFICE |
| TO: Dr. M. Finkel | | DIVISION |

SUBJECT: ANDA 80-515 Cyanocobalamin Injection

SUMMARY

Final typed approved letter.

The labeling(insert) requires some revision ("one case", "toxic effects rarely reported") however I gather from the memo of meeting between you and Dr. Clark on 9/16/71, you are willing to approve this application with this less than satisfactory labeling pending FDA quideline labeling for the product.

I have no major objections to the action of the letter.

/S/

10/18/71

| SIGNATURE | DOCUMENT NUMBER |
|---|---|

FORM FDH-2034 (11/66)