CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 083722Orig1s009

Name: Phytonadione Injection USP, l mg/0.5 ml

Sponsor: International Medication Systems, Limited

Approval Date: August 5, 1987

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 083722Orig1s009

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Reviews / Information Included in this Review

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Microbiology Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 083722Orig1s009

APPROVAL LETTER

ANDA 83-722/S-009

International Medication Systems Limited
Attention: Annette Riley
1886 Santa Anita Avenue
South El Monte, CA 91733

AUG 5 1987

Dear Ms. Riley:

Reference is made to your supplemental new drug application submitted pursuant to Section 314.70 of the Regulations, dated February 25, 1987, regarding your abbreviated new drug application for Phytonadione Injection USP, 1 mg/0.5 mL.

The supplemental application provides [redacted] (b) (4) of the vial injector.

Also referenced is your communication dated May 20, 1987.

We have completed the review of this supplemental application and it is approved. Our letter of March 1, 1976 detailed the conditions relating to the approval of this abbreviated application.

The material submitted is being retained as part of your application.

Sincerely yours,

Leon C. Johnson for 8-5-87

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

cy 8/4/87

HFN-237
CChang/MGoldman/7/31/87
8/3/87 bmc 3317d
Approval

MGoldman 8/4/87

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 083722Orig1s009

CHEMISTRY REVIEWS

ANDA 83-722/S-009 CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT

NAME AND ADDRESS OF APPLICANT:

IMS
South El Monte, CA

PURPOSE OF AMENDMENT/SUPPLEMENT

(b) (4) (sterilization) of vial injector.

DATE(S) OF SUBMISSION(S)

February 25, 1987 and May 20, 1987.

NAME OF DRUG	HOW DISPENSED
Phytonadione	Rx

DOSAGE FORM	POTENCY	STERILIZATION
Injection	1mg/0.5 mL	See below

RELATED IND/NDA/DMF

DMF (b) (4)

ESTABLISHMENT INSPECTION

EER sent 4/1/87. Approved 4/9/87.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

(b) (4) sterility data submitted. DMF (b) (4) OK.

PACKAGING

No change.

STABILITY

Protocol: No change.

Expiration Date: No change.

REMARKS AND CONCLUSION

MGoldman
Approval
3317d

MGoldman 8/4/87

ANDA 83-722/S-009 CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT

NAME AND ADDRESS OF APPLICANT:

IMS
South El Monte, CA

APR 6 1987

PURPOSE OF AMENDMENT

[redacted] (b) (4) (sterilization) of vial injector.

DATE(S) OF SUBMISSION(S)

February 25, 1987

NAME OF DRUG	HOW DISPENSED
Phytonadione	Rx

DOSAGE FORM	POTENCY	STERILIZATION
Injection	1 mg/0.5 mL	See below

RELATED IND/NDA/DMF

DMF [redacted] (b) (4)

ESTABLISHMENT INSPECTION

EER sent 4/1/87.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

[redacted] (b) (4) sterility data submitted. DMF [redacted] (b) (4) under review.

PACKAGING

No change.

STABILITY

Protocol: No change.

Expiration Date: No change.

REMARKS AND CONCLUSION

MGoldman
Review w/f
1413S

M Goldman
4/3/87

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 083722Orig1s009

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ANDA 83-722/S-009

International Medication Systems Limited
Attention: Annette Riley
1886 Santa Anita Avenue
South El Monte, CA 91733

APR 6 1987

[redacted] (b) (4)

Dear Ms. Riley:

Reference is made to your supplemental new drug application submitted pursuant to Section 314.70 of the Regulations, dated February 25, 1987, regarding your abbreviated new drug application for Phytonadione Injection USP, 1 mg/0.5 mL.

The supplemental application provides [redacted] (b) (4) of the vial injector.

We have reviewed the material submitted and have the following comments:

1. DMF [redacted] (b) (4) is under review. Remains OK 4/3/87

2. We have requested an establishment evaluation request for [redacted] (b) (4) OK 4/9/87
[redacted] (b) (4)

[redacted] (b) (4) Submit data demonstrating that the container/closure system [redacted] (b) (4)
[redacted] (b) (4)

Please let us have your response promptly.

Sincerely yours,

[redacted] (b) (4)

Marvin Seife 4/6/87

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

cc 4/3/87

HFN-237
CChang/MGoldman/tr/4/3/87
1413S
Review w/f

MGoldman 4/3/87