CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

85552

CHEMISTRY REVIEW(S)

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	STATEMENT DATE	NDA NUMBER 85-552

NAME AND ADDRESS OF APPLICANT (CITY AND STATE)

Chelsea Labs., Inc.
Inwood, NY 11696

Original
Amendment
Supplement
Resubmission
Correspondence
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

Pharmacological Category	Name of Drug	
anti-gout	probenecid & colchicine	
Dosage Form(s)	Potency(ies)	How Dispensed
tablet	0.5 g. and 0.5 mg.	Rx xxx OTC
Packaging/Sterilization	Samples	Related IND/NDA/MF
	satisfactory except need minor modification	

Labeling

satisfactory per MO REB 1-4-77

Biologic Availability

deferred by our Division (see other ANDA)

Establishment Inspection

satisfactory 1-31-77

Components, Composition, Manufacturing and Controls

components and dosage form meet compendium requirement

Remarks

Conclusion

approval

Reviewer

CChang

C Chang

Date 9-14-77

AF Number 85-552

ame and ~~Address~~ of Applicant (City and State) Chelsea Labs., Inc. Inwood, NY 11696	Original Amendment Supplement Resubmission xxx Correspondance Report Other
urpose of Amendment/Supplement Control info.	Date(s) of Submission(s) 7-1-77

harmacological Category	Name of Drug	
Anti-Gout	Probenecid + Colchicine	
osage Form(s)	Potency(ies)	How Dispensed
Tablet	0.5 g. + 0.5 mg.	R_x xxx OTC
ackaging/Sterilization	Samples	Related IND/NDA/NF
	Send to our lab on 7-20-77	

beling

Satisfactory per M.O. R. Barzilai 1-4-77

ologic Availability

deferred by our division (see other ANDA)

tablishment Inspection

Requested

nponents, Composition, Manufacturing and Controls

marks

wait for EIR & Lab results

clusion REv and wait

REVIEWER C. Chang 7-20-77 DATE C. Chang 7-21-77

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date

NDA Number
85-552

AF Number

Name and Address of Applicant (City and State)

Chelsea Labs., Inc.
Inwood, NY 11696

Original xxxxx
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

Pharmacological Category	Name of Drug	
anti-gout	probenecid + colchicine	12-14-76
Dosage Form(s)	**Potency(ies)**	**How Dispensed**
tablet	0.5 g. + 0.5 mg.	R_xXXXX OTC
Packaging/Sterilization	**Samples**	**Related IND/NDA/MF**
	REQUESTED	

Labeling

Satisfactory per MO REBarzilai 1-4-77

Biologic Availability

deferred (our Division decided) see other firms ANDA

Establishment Inspection

requested

Components, Composition, Manufacturing and Controls

Remarks

1. info on containers and closures
2. manufacturing precautions
3. samples and results
4. stability data needed.

Conclusion REV w/f

REVIEWER CChang C. Chang 2-8-77

DATE