CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

84279

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR BREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 84-279
		AF Number

ime and Address of Applicant (City and State)	
Danbury Pharmacal , Inc. **Danbury, CT 06810**	Original **XX** Amendment Supplement Resubmission Correspondance Report Other

urpose of Amendment/Supplement	Date(s) of Submission(s)
RIR attention	**November 4, 1976**

harmacological Category	Name of Drug	
urioscoric	**Probenecid with Colchicmbrine**	
osage Form(s)	Potency(ies)	How Dispensed
Tablet	**500 mg. with 0.5 mg.**	**Rxx** OTC
ackaging/Sterilization	Samples	Related IND/NDA/MF
NA		

abeling **Satosfactory previously per JBacsanyi**

iologic Availability

Deferred at present

tablishment Inspection

Satisfactory currently per NDD 322

omponents, Composition, Manufacturing and Controls

Satisfactory tests on components and drug

emarks

Approve application

onclusion **Approve JTaylor 11-19-76**

EVIEWER

DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

ANDA Number 84-279

AF Number 42-129

Name and Address of Applicant (City and State)

Danbury Pharmacal, Inc.
Danbury, CT 06810

Original
Amendment
Supplement
Resubmission xx
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
February 11, 1975

Pharmacological Category	Name of Drug	
gout	Probenecid with Colchicine	
Dosage Form(s)	**Potency (ies)**	**How Dispensed**
Tablet	Probenecid 500 mg. Colchicine 0.5 mg.	R_x xxx OTC
Packaging/Sterilization	**Samples**	**Related IND/NDA/MF**
light resistant amber polystyrne	Validated	12-383 for disintegration specs

Labeling
Satisfactory (JBacsanyi)

Biologic Availability
Deferred for this combination

Establishment Inspection
Re-requested

Components, Composition, Manufacturing and Controls
Satisfactory

Remarks
Satisfactory inspection

Conclusion Rec'd 8-25-75

REVIEWED

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 84-279

AE Number 42-129

Name and Address of Applicant (City and State)
Danbury Pharmacal, Inc.
Danbury, CT 06810

Original
Amendment
Supplement
Resubmission xxx
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
November 12, 1974

Pharmacological Category	Name of Drug	
gout	Probenecid with Colchicine	
Dosage Form(s)	Potency(ies)	How Dispensed
Tablet--C.T.	500 mg. Probenecid, 0.5 mg. Colchicine	Rx xxxx OTC
Packaging/Sterilization	Samples	Related IND/NDA/MF -
Amber polystyrene	Requested for validiation	12-383

Labeling
Previously satisfactory. Specific dosage recommendations on container were called to M.O. 's attention. (JBacsanyi)

Biologic Availability
Deferred for this combination.

Establishment Inspection
Previously requested

Components, Composition, Manufacturing and Controls

Controls applied to product require validation.

Remarks
1. Assay suggested for colchicine raw material/
2. Full I.D. test for colchicine raw material.
3. Samples, content uniformity methodology, and complete results.

/S/

Conclusion Rev w/f

JTaylor 1-17-74

REVIEWER /S/

DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date July 28, 1972	NDA Number 84-279 AF Number 42-129

Name and Address of Applicant (City and State)

Danbury Pharmacal, Inc.
Danbury, Connecticutt 06810

Original XXX
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

April 10, 1974

Pharmacological Category	Name of Drug	
Chronic gouty arthritis	Probenecid with Colchicine	
Dosage Form(s) Tablet	Potency (ies) Probenecid 500 mg. Colchicine 0.5 mg.	How Dispensed R_x [x] OTC [ ]
Environmental Impact Analysis Report Satisfactory	Samples REQUEST ON RESUBMISSION IF ANALYSIS IS REASONABLE	Related IND/NDA/NF(s)

Labeling

Satisfactory (Bacsanyi)
I checked with him on dosage statement on container label, but he felt it was satisfactory.

Biologic Availability

Deferred

Establishment Inspection

Inspection was requested 4-12-74 by Millar because of recent recalls due to mislabeling.

Components, Composition, Manufacturing and Controls

See below.

10. Container and closure specifications since colchicine is light sensitive.

Remarks

1. Omission of I.D. tests for finished dosage form.
2. No standard used in colchine analysis--just extinction coefficient.
3. Gastric fluid used instead of water for disentegration.
4. No content uniformity analysis for colchicine.
5. Clarify limits on weight variation.
6. Omission of microbial limit test for Primojel.
7. Omission of specs for process.
8. p. 26 assay procedure for probenecid is unintelligible.
9. N.F. XXI referenced for ethylcellulose. Request supplier specs.
10. Povidone modified test for aldehydes in 3rd supplement omitted.

Conclusion Rec w/f

/S/

6-24-74

TYPED

DATE