CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

83221

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-221 10-156 AE Number

Name and Address of Applicant (City and State)

Bolar Pharmaceutical Co. Inc.
Copiague, NY 11726

Original
Amendment XXXXX
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

amended analytical procedures

Date(s) of Submission(s)

2-7-75

Pharmacological Category	Name of Drug	
anti-gout	probenecid with colchicine	
Dosage Form(s) tablet	Potency(ies) probenecid 500 mg. colchicine 0.5 mg.	How Dispensed R_x XXXXX OTC
Packaging/Sterilization polyethylene bottles	Samples tested-refer to DAL-DO report 12-2-74	Related IND/NDA/DF

Labeling

satisfactory per medical officer's review of 4-10-73

Biologic Availability

deferred

Establishment Inspection

satisfactory ref: HFD-322 memo 3-20-75 based on 7/17/74 inspection

Components, Composition, Manufacturing and Controls

satisfactory

Remarks

approval majarski

/S/ 4/3/75

Conclusion

REVIEWER DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-221 AE Number 10-156

Name and Address of Applicant (City and State)

Bolar Pharmaceutical Co., Inc.
Copiague, NY 11726

Original ____
Amendment ____
Supplement ____
Resubmission ____
Correspondance ____
Report ____
Other FDA initiation

Purpose of Amendment/Supplement

Date(s) of Submission(s)

none

Pharmacological Category	Name of Drug	
anti-gout	probenecid with colchicine	
Dosage Form(s)	Potency(ies)	How Dispensed
tablet		R_x OTC
Packaging/Sterilization	Samples	Related IND/NDA/MF:
polyethylene bottles		

Labeling

satisfactory

Biologic Availability

deferred

Establishment Inspection

satisfactory

Components, Composition, Manufacturing and Controls

see below,

Remarks

The Dallas District has indicated that when certain precautions and errors are taken into account the method will comply with the representations set forth in the application.

Firm is advised of precautions and errors, and requested to revise and resubmit

rev w/f majarski /S/ 1/24/75

Conclusion

REVIEWER DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-221 AE Number 10-156

Name and Address of Applicant (City and State)

Bolar Pharmaceutical Co., Inc.
Copiague, NY 11726

Original
Amendment
Supplement
Resubmission
Correspondance XXXXX
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

9-9-74

Pharmacological Category	Name of Drug	How Dispensed
anti-gout	probenecid with colchicine	R_x XXXXX OTC
Dosage Form(s)	Potency(ies)	
tablet		
Packaging/Sterilization	Samples	Related IND/NDA/MF
polyethylene bottles	sent to Dallas District for validation	

Labeling

satisfactory

Biologic Availability

deferred

Establishment Inspection

satisfactory

Components, Composition, Manufacturing and Controls

satisfactory

Remarks

contingent on a satisfactory laboratory report - this application is approvable.

approvable majarski

11/6/74

Conclusion

REVIEWER DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-221 AF Number 10-156

Name and Address of Applicant (City and State)

Bolar Pharmaceutical Co., Inc.
Copiague, NY 11726

Original
Amendment
Supplement
Resubmission xxxxx
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
4-12-74

Pharmacological Category	Name of Drug	How Dispensed
anti-gout	probenecid with colchicine	
Dosage Form(s) tablet	Potency(ies) probenecid 500 mg. colchicine 0.5 mg.	How Dispensed R_x xxxxxxx OTC
Packaging/Sterilization polyethylene bottles	Samples received in sample room 1 bottle 100's # 063192 (as per J. Beckwith 7-12-74)	Related IND/NDA/NF

Labeling

satisfactory4-10-73

Biologic Availability

deferred

Establishment Inspection

satisfactory per HFD-340 memo of 10-11-73

Components, Composition, Manufacturing and Controls

additional information

Remarks

firm is requested to comment on comprehensive specifications

rev. w/f. majarski /S/ 7/23/74

Conclusion

[illegible] FOR [illegible] APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-221 AF Number 10-156

Name & Address of Applicant (City and State)

Solar Pharmaceutical Co., Inc.
Copiague, NY 11726

Original
Amendment
Supplement
Resubmission XXX
Correspondance
Report
Other

Type of Amendment/Supplement

Date(s) of Submission(s)

9-17-73

(received 11-27-73)

Pharmacological Category	Name of Drug	
anti-gout agent	probenecid with colchicine	
Dosage Form(s)	Potency (ies)	How Dispensed
tablet	probenecid 500 mg. colchicine 0.5 mg	R_x XX OTC
Environmental Impact Analysis Report	Samples	Related IND/NDA/AF(s)
	submitted 11-27-73	

Labeling

satisfactory per medical officer's review of 4-10-73

Biologic Availability

deferred

Establishment Inspection

satisfactory per BD-340 memo of 10-11-73

Components, Composition, Manufacturing and Controls

firm to submit actual/numerical specifications for the final dosage form
firm also to submit methodology appropriate to thes specs and to submit test data.

Bioequivalence

Recommendation

rev w/f majarski

/S/ 12/7/73

DATE

...REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	ORIGINAL ☐ SUPPLEMENT ☐
...e & Address of Applicant (City & State) **Bolar Pharmaceutical CO., Inc.** **Copaigue, New York 11726**		NDA Number **83-221** Supplement Date and No...
...e of Drug **probenecid with colchicine**	Nonproprietary Name	Amendment Date(s) **2-7-73** **3-3-73**
...rpose of Supplement		Other Date(s)
...rmacological Category **anti-gout agent.**	How Dispensed R_x [XX] O.T.C. ☐	AE Number **10-156** Related IND/NDA/DF(s)
...sage Form(s) **tablet**	Potency (ies) **500 mg. with 0.5 mg colchicine**	

...tisfactory ☐ Labeling
Date Due ~~satisfactory per~~ **medical officer**

...isfactory ☐ Components, Composition, Manufacturing and Controls
Date Due **additional information**

...isfactory ☐ Biologic Availability
Date Due **deferred 6-26-72**
Is data on current formulation? YES ☐ NO ☐

...isfactory ☐ Probably or Possibly Effective Indications (if in labeling)
Date Data Due _____

...ablishment Inspection	Recalls
referred to compliance 4-23-73	

...relabeling of drug in commercial channels required? YES ☐ NO ☐
...so, what level:

...arks

Combination preparation is not a compendium item, although each active ingredient is a compendium material. Firm has submitted procedure for assay of the tablet. Request samples for validation of this method.

Request submitted to BD-105 on 2-9-73 for evaluation of status of firm.

...clusions

rev w/f majarski (S) 5/14/73

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 83-221

Name and Address of Applicant (City and State)
Rolar Pharmaceutical Co., Inc.
Copiague, New York 11726

Original ____

Amendment XXX

Supplement ____

Other ____

Name of Drug: probenecid with colchicine

Nonproprietary Name

Purpose of Supplement

Date(s) of Submission(s): 1-17-73

Pharmacological Category: anti gout agent

How Dispensed: R_x [XX] O.T.C. [ ]

Dosage Form(s): tablet

Potency (ies)
Probenecid 500 mg.
Colchicine 0.5 mg.

AF Number 10-156

Related IND/NDA/MF

Satisfactory [ ] Labeling
Date Due draft labeling satisfactory

Satisfactory [ ] Components, Composition, Manufacturing and Controls
Date Due additional information

Satisfactory [ ] Biologic Availability
Date Due deferred for combination preparation used for gout
Is data on current formulation? YES [ ] NO [ ]

Satisfactory [ ] Probably or Possibly Effective Indications (if in labeling)
Date data Due ____

Establishment Inspection
requested 2-9-73

Recalls

Is relabeling of drug in commercial channels required? YES [ ] No [ ]
If so, what level?

Remarks

request final printed labeling
submit specifications and tests for final dosage form. This is not a compendium item (i.e. combination) therefore, firm should submit a more detailed procedure.

Conclusions

rev w/f majarski

/S/ 2/20/73

OR SUPPLEMENT | Statement Date | 83-221

Name and Address of Applicant (City and State)
Bolar Pharmaceutical Co., Inc.
Copiague, New York 11726

Original XXX
Amendment
Supplement
Other

Name of Drug | Nonproprietary Name
Probenecid with Colchicine

Purpose of Supplement

Date(s) of Submission(s)
1 9-12-72

Pharmacological Category
antigout agent

How Dispensed
R_x [X] O.T.C. [ ]

Dosage Form(s)
tablet

Potency (ies)
Probenecid 500 mg
Colchicine 0.5 mg.

AF Number
10-156

Related IND/NDA/MF

Satisfactory [ ] Labeling
Date Due revise package insert per M.O.R.

Satisfactory [ ] Components, Composition, Manufacturing and Controls
Date Due ~~additional information~~

Satisfactory [ ] Biologic Availability
Date Due deferred for combination preparation used for gout
Is data on current formulation? YES [ ] NO [ ]

Satisfactory [ ] Probably or Possibly Effective Indications (if in labeling)
Date data Due

Establishment Inspection
2/7,8,9,15/72 satisfactory

Recalls

Is relabeling of drug in commercial channels required? YES [ ] No [ ]
If so, what level?

Remarks

final printed container labels
revised package insert
clarify dicalcium phosphate
submit test methods for assay
submit test methods used ~~in~~ for final dosage form - the combination is not a compendium item,

Conclusions

rev w/f ma jarski |S| 12/26/72