CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

84321

CHEMISTRY REVIEW(S)

[illegible] REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 84-321 1-258 AF Number

and Address of Applicant (City and State)

Beecham-Massengill Pharmaceuticals
Bristol, TN 37620

Original xxxxx
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

received 5-20-74

Pharmacological Category	Name of Drug	
anti-gout	probenecid with colchicine	
Dosage Form(s)	Potency(ies)	How Dispensed
tablet	probenecid 0.5 g. colchicine 0.5 mg.	R_x xxxxxx OTC
Packaging/Sterilization	Samples	Related IND/NDA/MF
request	final dosage form for methods validation	

Labeling

satisfactory draft per medical office's review of 6-14-74

Biologic Availability

not required for combination

Establishment Inspection

requested 7-10-74

Components, Composition, Manufacturing and Controls

additional information requested - note question on significant figures in formula

Remarks

r w/f majarski

/S/ 7/18/74

Conclusion

REVIEWER DATE

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date	84-321 AF Number

Name and Address of Applicant (City and State)
Beecham Laboratories
Bristol, TN 37620

Original
Amendment
Supplement
Resubmission
Correspondance XXXXX
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
2-4-76

Pharmacological Category	Name of Drug	
anti-gout	probenecid with colchicine	
Dosage Form(s) tablet	Potency(ies) probenecid 0.5 g. colchicine 0.5 mg.	How Dispensed R_x x xxxx OTC
Packaging/Sterilization included	Samples report of 2-4-57 addendum of 3-21-75 addendum of 1-22-76	Related IND/NDA/MF

L ling
satisfactory per medical officer's review of 10-11-74

Biologic Availability
deferred

Establishment Inspection
related HFD-322 meo of 1-12-76
based on inspection of 5-12-75 satisfactory

Components, Composition, Manufacturing and Controls

Remarks The firm points out that state of the art in is variable and indicates that the method works satisfactorily on their equipment.

approval majarski

|S| 3/9/76

C lusion

REVIEWER DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	ANDA Number 84-321 AF Number

Name and Address of Applicant (City and State)	Original / Amendment / Supplement / Resubmission / Correspondance / Report / Other
Beecham Laboratories Bristol, TN 37620	xxxxx

Purpose of Amendment/Supplement	Date(s) of Submission(s)
liquid chromatographic assay procedure	8-11-75

Pharmacological Category	Name of Drug	
anti gout	probenecid with colchicine	
Dosage Form(s)	**Potency (ies)**	**How Dispensed**
tablet		R_x xxxxx OTC
Packaging/Sterilization	**Samples**	**Related IND/NDA/MF**
	Atlanta District report 1-23-76	

Labeling

Biologic Availability

Establishment Inspection

Components, Composition, Manufacturing and Controls

Remarks

Laboratory considers the procedures non-regulatory - firm advised of comments

rev w/f majarski

/S/ 1/28/76

Conclusion

REVIEWER DATE

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 84-321

AF Number 1-258

Name and Address of Applicant (City and State)
Beecham-Massengill Pharmaceuticals
Bristol, TN 37620

Original
Amendment
Supplement
Resubmission XXXXX
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
12-17-74

Pharmacological Category
anti-gout

Name of Drug
probenecid with colchicine

Dosage Form(s)
tablet

Potency(ies)
probenecid 0.5 g.
colchicine 0.5 mg.

How Dispensed
R_x xxxxx
OTC

Packaging/Sterilization
included

Samples
analyzed see report of 2-4-75 and addendum 3-21-75

Related IND/NDA/MF

Labeling
satisfactory per medical officer's review of 10-11-74

Biologic Availability
deferred

Establishment Inspection
satisfactory per HFD-340 memo 10/30/74 (related)

Components, Composition, Manufacturing and Controls
Laboratory has raised questions on control methodology
firm is to explain why disintegration/dissolution is not part of stability

Remarks

rev w/f majarski

/S/ 6/2/75

Conclusion

REVIEWER

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	84-321 AF Number 1-258

Name and Address of Applicant (City and State)		
Beecham-Massengill Pharmaceuticals Bristol, TN 37620		Original Amendment Supplement Resubmission XXXXX Correspondance Report Other
Purpose of Amendment/Supplement		Date(s) of Submission(s) 9-5-74
Pharmacological Category anti-gout	Name of Drug probenecid with colchicine	
Dosage Form(s) tablet	Potency(ies) probenecid 0.5 g. colchicine 0.5 mg.	How Dispensed Rx XXXXX OTC
Packaging/Sterilization	Samples sent to Atlanta district 11-12-74	Related IND/NDA/MF

Labeling

satisfactory per medical officer's review of 10-11-74

Biologic Availability

deferred

Establishment Inspection

satisfactory: HFD-340 memo approval for 84-478 10/30/74

Components, Composition, Manufacturing and Controls

see below

Remarks

firm originally provided for a % excess of colchicine - firm now advises that based on stability studies only a % excess is needed. Firm is to revise spec sheets to provide for %, submit the stability data for inclusion in the application.

rev w/f majarski /S/ 11/22/74

Conclusion

REVIEWER DATE