

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**84321**

**ADMINISTRATIVE DOCUMENTS**

<p style="text-align: center;"><b>NOTICE OF APPROVAL</b> NEW DRUG APPLICATION OR SUPPLEMENT</p>		NDA NUMBER <b>84-321</b>
		DATE APPROVAL LETTER ISSUED <b>MAR 11 1978</b>
TO:  Press Relations Staff (PA-40)	FROM:  <input checked="" type="checkbox"/> Bureau of Drugs  <input type="checkbox"/> Bureau of Veterinary Medicine	
<p>Forward original <b>ABBREVIATED</b> application to the Bureau of Drugs if an approval letter has been issued and the date of approval has been entered on the label.</p>		
TYPE OF APPLICATION <input type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO NDA <input checked="" type="checkbox"/> ABBREVIATED ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO ANDA		CATEGORY <input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG <p style="text-align: center;"><b>probenecid with colchicine</b></p>		
DOSAGE FORM <p style="text-align: center;"><b>tablet</b></p>		HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC
ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)  <p style="text-align: center;"><b>probenecid      0.5 g.</b> <b>colchicine      0.5 mg.</b></p>		
NAME OF APPLICANT (Include City and State)  <p style="text-align: center;"><b>Beecham Laboratories</b> <b>Bristol, TN 37620</b></p>		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY  <p style="text-align: center;"><b>anti-gout</b></p>		
COMPLETE FOR VETERINARY ONLY		
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLETE FOR SUPPLEMENT ONLY		
CHANGE APPROVED TO PROVIDE FOR		
FORM PREPARED BY		
NAME <b>majarski</b>	DATE	
FORM APPROVED BY		
NAME <b>jlmeyer</b>	DATE	

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

TO : W. Michael Rogers  
Director of Chemistry  
Atlanta Regional Laboratory (HFR-460)

DATE: September 5, 1975

FROM : Mary Ann Jarski - HFD-530

SUBJECT: Assay validation for:  
84-321 Probenecid with Colchicine Tablets  
Beecham Laboratories  
Bristol, TN 37620

Per our telephone conversation of 9-5-75, enclosed find procedure for assay of Probenecid with Colchicine tablets. Validation is requested. Samples and standards are being forwarded to you directly by the firm.

/s/

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 9-5-75
FROM: mary ann jarskt - HFD-530		OFFICE
TO: file 84-321		DIVISION
SUBJECT: Telephone conversation between J.L. Meyer HFD-530 and Ernest W. Cornett		
<p>SUMMARY</p> <p>Beecham Laboratories.</p> <p>Re: Beecham Laboratories communication of 8-11-75 relating to their application 84-321 Probenecid with Colchicine</p> <p>In the referenced communication the firm advised that (a) the dissolution time had been verified at ___ minutes and (b) the assay had been changed to a _____ method.</p> <p>Per telephone conversation with the firm, Mr. Meyer indicated (a) the ___ minutes was inconsistent with data they had submitted for the application ( however, this was not regarded as a significant point since U.S.P. allows a ___ minute disintegration time for Probenecid tablets - therefore the FDA finding of ___ minutes is probably consistent with this specification) and (b) the _____ assay would have to be validated and samples and standards should be sent directly to the Atlanta District.</p>		
SIGNATURE <i>/S/</i>		DOCUMENT NUMBER

<b>MEMO RECORD</b>	<b>AVOID ERRORS PUT IT IN WRITING</b>	<b>DATE</b> 8/29/75
<b>FROM:</b> Mary Ann Jarski HFD-530		<b>OFFICE</b>
<b>TO:</b> Sander W. Bellman HFD-130		<b>DIVISION</b>
<b>SUBJECT:</b> Assay validation		
<p><b>SUMMARY</b></p> <p>ANDA 84-321 Probenecid w colchicine Beecham-Massengill Bristol Tennessee</p> <p>Per our telephone conversation of 8-29-75, a district assignment is requested for validation of firm's new assay procedure -see enclosure</p> <p>The Atlanta district did the original work on this ANDA</p> <p>Thank you</p>		
<b>SIGNATURE</b>  /S/		<b>DOCUMENT NUMBER</b>

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 5-21-75
FROM: ma jarski		OFFICE
TO: file 84-321		DIVISION
SUBJECT: Telephone Conversations		
<p>SUMMARY</p> <p>1/3/74</p> <p>Re: 84-321 Probenecid &amp; Colchicine Tablets - Beecham-Massengill</p> <p>Received a call for John Ross of the Atlanta District that the support for the procedure was not available (no longer made by the manufacturer) I indicated I would call the firm and arrange for them to provide an answer</p> <p>Spoke to Mr. Horning and Mr. Jackobson of Beecham-Massengill I requested that they call the Atlanta District about the plate</p> <p>3/19/75</p> <p>Call to E. Carley of the Atlanta District concerning their results vs manufacturers results on colchicine assay; <math>R_f</math> values and <math>T_{90}</math> dissolution. Mr. Carley indicated he would submit detailed comments.</p>		
SIGNATURE	DOCUMENT NUMBER	

<b>MEMO RECORD</b>	<b>AVOID ERRORS PUT IT IN WRITING</b>	<b>DATE</b> 11-6-74
<b>FROM:</b> ma jarski - generic drugs - HFD-107		<b>OFFICE</b>
<b>TO:</b> john marcus - HFD-130		<b>DIVISION</b>
<b>SUBJECT:</b> 14-321 Probenecid & Colchicine Tablets		
<b>SUMMARY</b> Beecham-Massengill Pharmaceuticals Bristol, Tennessee 37620  Attached find methodology for subject ANDA. Please assign District laboratory for validation.  J  S		
<b>SIGNATURE</b>		<b>DOCUMENT NUMBER</b>