CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

84321

CORRESPONDENCE

NDA [redacted]

JAN 30 1976

Beecham Laboratories
Attention: Ernest H. Cornett
501 Fifth Street
Bristol, TN 37620

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Probenecid 0.5 g. with Colchicine 0.5 mg. Tablets.

Reference is also made to your communication dated August 11, 1975, relating to specifications and tags proposed.

Our laboratories have completed the evaluation of your laboratory procedures and comment as follows:

The dosage form was assayed according to the NDA method.

The assay for colchicine was performed on a 20 tablet composite and 10 individual tablets. The assay for probenecid was performed on a 20 tablet composite. The results follow.

1. Colchicine - 107.4%, 107.[redacted]% (two injections from one composite, individual tablets (one [redacted] range [redacted]%, average = 99.4%.

2. Probenecid - [redacted]%, 100.2%, 99.9% (three injections from one composite).

In the colchicine assay, [redacted] was noted from the U.V. scans showed some interference along the leading edge of the peak. However, it was not severe enough to interfere with the colchicine and chromatography assay [redacted]

In the probenecid assay the interference was much more [redacted] calculation impossible.

It was [redacted] the probenecid assay preparation without programming and to study the ratio of acetonitrile to [redacted] to hold constant at [redacted]. When this was done, satisfactory system suitability results were obtained.

It is felt that the interference shown in both assays was due to the program speed. The speed with wich the ration was changed appears to be too fast for the mixing chamber to handle.

Note that the interference was less in the slower of the two programs. The colchicine is programmed over [illegible] in 8 minutes and the probenecid over [illegible] in 5 minutes.

Several runs were made on the probenecid program without any injection being made and this same interference was noted.

The assay method as written is considered unsuitable for regulatory work. However, it is felt that the problem discussed above is a problem which might not occur in all   instruments and with some adjustments could be made to work. It appears that it might not be necessary to use a program on this assay at all and that satisfactory results could be obtained by finding the optimum [illegible] combination for each compound and running at these conditions.

Please let us have your response promptly.

Sincerely yours,

/S/ 1/30/76

[illegible], M.D.
Director
Division of [illegible] Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
[illegible]
Dup
HFD-[illegible] /S/ 1/28/76
HFD-[illegible]
JLMayer/[illegible]
R/D init. JMayer/MSeife/1-28-76
Final typing/rt/1-28-76
rev w/f /S/ 1/29/76

NDA 84-321

MAR 23 1982

Beecham Laboratories
Attention: Lee Hopping
501 Fifth Street
Bristol, TN 37620

Gentlemen:

We acknowledge the receipt of your communication dated March 9, 1982 requesting withdrawal of approval of your abbreviated new drug application for Probenacid with Colchicine Tablets.

In compliance with your request and in accord with sections 314.115 of the Federal Food, Drug, and Cosmetic Act, action will be taken to withdraw approval of the application. Appropriate notice will be given by publication in the Federal Register in accord with 314.116.

This withdrawal will not prejudice any future filing of the application. You may request that the information in this application be considered in connection with any resubmissions.

Sincerely yours,

/S/ 3/23/82

Marvin Seife, M.S.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

NASH-DO DUP HFD-530
DRosen/MSeife
ft/cjl/3-22-82
approved w/drawal

BEST POSSIBLE COPY

NDA [illegible]

AF Y-250

JUN 1 2 1974

[illegible] Pharmaceuticals
Division of [illegible] Incorporated
Attention: Mr. [illegible]
Bristol, Tennessee [illegible]

Gentlemen:

We acknowledge the receipt of your [illegible] new drug application [illegible] pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NAME OF DRUG: Probenecid and Colchicine Tablets

DATE OF COVER LETTER: May 15, 1974

DATE OF RECEIPT: May [illegible], 1974

We will correspond with you further after we have had the opportunity to review the application.

We would also like to call to your attention the Federal Register of [illegible]

Please [illegible] concerning this application [illegible]

cc: [illegible]
[illegible]
[illegible]
[illegible]

Sincerely yours,

/S/ 6/12/74

[illegible]
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

ACK: /S/ 6/14/74
/S/

NDA 84-321

AF 1-258

JUL 19 1974

Beecham-Massengill Pharmaceuticals
Division of Beecham Incorporated
Attention: Mr. Lee Herring
Bristol, TN 37620

Gentlemen:

Reference is made to your abbreviated new drug application dated May 16, 1974, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Probenecid 0.5 g. with Colchicine 0.5 mg. Tablets.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. Final printed labeling identical in content to the submitted drafts.

2. Three copies of the completed and signed form 356H (copies are enclosed for your convenience).

3. The rationale for including a 1 ounce of colchicine in your formulation. Additionally, clarification is requested on the accuracy of your "amount per tablet" figures.

4. Assurance that the specifications and tests applied to the final dosage form and components are adequate to assure identity, strength, quality and purity.

   (a) clarify the chemical identity of and include the referenced technical data sheet.

   (b) revise the specifications for the final dosage form to include (1) identity procedures for probenecid and colchicine and (2) dissolution procedures for probenecid.

5. Noting the "extremely poisonous" and light sensitive nature of colchicine, include an expanded manufacturing outline clarifying any special procedures/precautions observed in the operations.

6. Include information on containers and closures.

To expedite the processing of this application we are requesting samples of the final dosage form together with your analytical results for their testing (noting the comments as above).

Please let us have your response promptly.

Sincerely yours,

/S/ 7/18/74

Marvin Seife, M.D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

Enclosure: Form 356H

cc:
ATL-DO
Dup
HFD-107
HFD-106
HFD-13
HFD-8
VVKarusaitis/JLMeyer/MAJaraki
R/D init. MSeife/JMeyer/7-12-74
Final Typing/rt/7-16-74
rev w/f

Majarski 7/18/74

7/18/74

JMMeyer 7/18/74

NDA 84-321

AF 1-258

NOV 26 1974

Beecham-Massengill Pharmaceuticals
Division of Beecham Incorporated
Attention: Lee Bowring
Bristol, TN 37620

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Probenecid 0.5 g. with Colchicine 0.5 mg. Tablets.

Reference is also made to your communication dated September 5, 1974, enclosing manufacturing information and samples.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. "Laboratory Standard Manual PROBENECID WITH COLCHICINE TABLETS (Control Procedures)" revised to provide for the 5 assays of colchicine.
2. A full description of, and the data derived from, studies of the stability of the drug, including your intent with respect to expiration dating.

Please let us have your response promptly.

Sincerely yours,

/S/ 11/22/74

[redacted], M.S.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
ATL-DO
dup
HFD-107 HFD-106
HFD-13 HFD-8
VVKarusaitis/JLMeyer/[redacted]Jarski
R/D init. JLMeyer, MSeife 11/21/74
Final typing bbo 11/21/74
rev. w/f

JLMeyer 11/22/74 VVK/Maura Jarski 11/22/74

NDA 84-325

AF 1-258

Beecham-Massengill Pharmaceuticals
Division of Beecham Inc.
Attention: Lee Bunning
501 Fifth Street
Bristol, TN 37620

JUN 3 1975

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Probenecid 0.5 g. with Colchicine 0.5 mg. Tablets.

Reference is also made to your communication dated December 17, 1974, relating to the application.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

re: Item II, Stability: The rationale for not including disintegration and/or dissolution testing in your stability program.

Our Laboratories have evaluated your samples and methodology and comment as follows:

In the assay for colchicine it was noted that the U.V. curve showed a distorted hemline. It was felt that this distortion was due to the presence of approximately [redacted] times more probenecid than colchicine. If a base line correction is applied to the calculations, it appears that the interference was not significant; however, should the desired amount of colchicine be near the upper or lower limits, the [redacted] could cause the assay results to be in error. This assay [redacted] considered to be unsuitable for regulatory work. The [redacted] may be greatly improved by going through some method of separating the probenecid and colchicine before running the U.V. spectra.

The [redacted] plates showed a difference in RF times from the certificate of analysis. Since these differences could be attributed to differences in the [redacted] plate lot or differences in solvents, and since the standard and sample spot did match, it was felt that this difference was not

significant. However, it was also noted that relatively large tailing spots followed closely behind colchicine. This did not negate positive identification in this case, but, as in the case of the assay, it could result in obscuring the colchicine spot.

The dissolution time assay gave a T_{99} minutes. The certificate of analysis gives a value of minutes. It was felt that the manufacturer's result was either low or a misprint. It was noted that it took minutes for total disintegration to take place.

Please let us have your response promptly.

Sincerely yours,

/S/ 6/3/75

Marvin Wolfe, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Enclosure: laboratory results

cc:
AKL-DO
Dup
HFD-530
HFD-614
HFD-616 [illegible] 5/75
JLMeyer/MkFerrell
R/D init. MWolfe/JLMeyer 5-22-75
Final typing/rt/5-30-75
rev w/f
JLMeyer 6/3/75

Beecham
laboratories

EXECUTIVE OFFICES 501 FIFTH STREET, BRISTOL, TENNESSEE 37620 615-764-5141

NDA 84-321

NDA ORIG AMENDMENT

February 4, 1976

Marvin Seife, M. D.
Director
Division of Generic Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Seife:

Re: NDA 84-321 - Probenecid with Colchicine Tablets
Your letter of January 30, 1976

The above referenced letter apparently contains the uninterpreted comments from FDA's testing laboratories regarding the analytical methodology contained in NADA 84-321. I would like to offer response to those comments.

The laboratory noted that some "interference" was present in the U. V. spectrum exhibited by the assay solutions and concluded the methodology was "unsuitable for regulatory purposes." This conclusion is totally unwarranted and unjustified.

The chemist himself acknowledges that the method gives satisfactory results when appropriate adjustments are made in the instrumentation. Anyone familiar with knows that each instrument, because of peculiarities in column packings, will exhibit different elution times. Therefore, minor adjustments must be made to offset a given column's individual characteristics. When the chemist did so, the presence of "interference" was removed and the method performed satisfactorily.

Now to approach the question of the nature of the "interference," I quote from the letter

"Several runs were made on the probenecid program without any injection being made and this same interference was noted." (Emphasis added.)

The chemist thus acknowledges that the "interferences" were in fact originating within his instrument and yet he continued to attribute them to the methodology being employed.

Dr. Seife, we believe this application should be approved. Therefore, in order to preserve our rights under §314.111(b), we respectfully request your timely consideration of this matter.

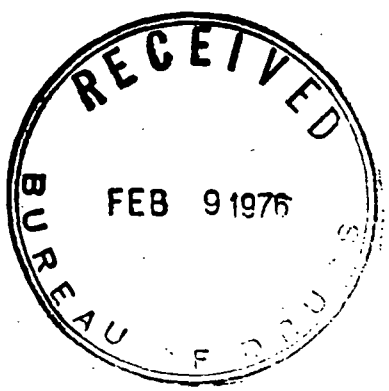
Sincerely,

Ernest W. Cornett

Ernest W. Cornett
Manager, Regulatory Affairs

/bc

Certified Mail
Return Receipt Requested



With this commitment to use for quality control analysis, Beecham will be relying on two highly specific systems to identify colchicine -

Therefore, there is no possibility of the presence of colchicine being obscured.

The FDA laboratory reported a T_{90} minutes as dissolution time and noted Beecham's certificate of analysis gave a value of minutes. Beecham laboratory personnel have repeated the analysis, and confirmed the reported T_{90} time of minutes. We cannot explain the difference unless perhaps the FDA laboratory was either using simulated gastric fluid as a dissolution medium or following the NFXIII, Method I, which employs a Rotating Basket Procedure. Beecham's method is based on the Stoll-Gershberg Procedure, NFXIII, Method II, and uses simulated intestinal fluid without pancreatin as the dissolution medium because probenecid is practically insoluble in a water and acid media. For your convenience, submitted herewith is a copy of Beecham's dissolution data.

Dr. Seife, this rather short filing was originally filed in May of 1974. Since then, we have been asked to supply additional materials and/or data on three different occasions. In all fairness, it would seem these requests could have been the subject of a single request to avoid unreasonable delay.

In view of the age of the original filing, I respectfully request early review of the data submitted herewith.

Sincerely,

Ernest W. Cornett

Ernest W. Cornett
Manager, Regulatory Affairs

/bc

Attachments

Certified Mail
Return Receipt Requested

Orig

Beecham laboratories

Rec'd 11-

EXECUTIVE OFFICES 501 FIFTH STREET, BRISTOL, TENNESSEE 37620 615-764-5141

NDA 84-321

RESUBMISSION

NDA ORIG AMENDMENT

August 11, 1975

Marvin Seife, M. D.
Director
Division of Generic Drug Monographs
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Dear Dr. Seife:

Re: NDA 84-321 - Probenecid with Colchicine
Your letter of June 3, 1975

In response to the above referenced letter requesting additional information, the following is submitted.

Stability: By Amendment dated December 17, 1974, Beecham furnished the analytical methodology used for stability testing of its probenecid with colchicine tablets. Included therewith was accumulated stability data. Please note that on page 7 of that Amendment there is a specification for tablet disintegration of not more than minutes. Disintegration testing has been performed at each testing interval in the stability testing program. Submitted herewith are updated accumulated stability testing data, including results of disintegration tests.

Noted in your letter of June 3 were comments and observations made by laboratory personnel during their evaluation of the submitted methodology. Specifically, the assay method was judged to be unsuitable for regulatory work, and certain questions were raised regarding the method used to confirm the identity of colchicine.

In the Amendment of December 17, Beecham submitted methodology used to analytically determine the intact colchicine molecule in its stability program (see pp. 7 and 8). The method employed
Submitted herewith is a more detailed description of the method which will be used by Beecham for both stability and quality control analysis on future production batches.

Beecham-Massengill Pharmaceuticals
DIVISION OF BEECHAM INC. BRISTOL, TENNESSEE 37620

RESUBMISSION
NDA ORIG AMENDMENT

EXECUTIVE OFFICES
501 Fifth Street

BMP

615-764-5141

NDA 84-321

December 17, 1974

Marvin Seife, M.D., Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Dear Dr. Seife:

Re: Probenecid and Colchicine Tablets
NDA 84-321

This is to acknowledge receipt of your letter of November 26, 1974 in which you requested additional information in reference to our Abbreviated New Drug Application for Probenecid and Colchicine Tablets, NDA 84-321.

For your convenience, the additional information is set forth in a sequence corresponding to the list of items included in your correspondence of November 26, 1974. Thus, the information given under Item 1 is our response to the first item noted in your letter, etc. Each item is prefaced by a verbatim excerpt from your letter.

We will appreciate the consideration of the enclosed submission at your earliest convenience, and trust that you will now be able to take favorable action on NDA 84-321.

Sincerely,

Lee Horning

Lee Horning
Regulatory Affairs Coordinator

/bc

Attachments

Certified Mail
Return Receipt Requested

RECEIVED
DEC 24 1974
BUREAU OF DRUGS

Beecham-Massengill Pharmaceuticals

RESUBMISSION

Orig.

DIVISION OF BEECHAM INC. BRISTOL, TENNESSEE 37620

NDA ORIG AMENDMENT

EXECUTIVE OFFICES
501 Fifth Street

BMP FPL 615-764-5141

NDA 84-321

September 5, 1974

Marvin Seife, M. D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Dear Dr. Seife:

Re: Probenecid and Colchicine Tablets
NDA 84-321

This is to acknowledge receipt of your letter of July 19, 1974, in which you requested additional information in reference to our Abbreviated New Drug Application for Probenecid and Colchicine Tablets, NDA 84-321.

For your convenience, the additional information is set forth in a sequence corresponding to the list of items included in your correspondence of July 19, 1974. Thus, the information given under Item 1 is our response to the first item noted in your letter, etc. Each item is prefaced by a verbatim excerpt from your letter.

We trust that the additional information provided in the enclosed submission will permit you to take prompt and favorable action on NDA 84-321.

Sincerely,

Lee Horning

Lee Horning
Regulatory Affairs Coordinator

Enclosures

Certified Mail
Return Receipt Requested

RECEIVED
SEP 10 1974
BUREAU OF DRUGS

Beecham-Massengill
Pharmaceuticals
DIV. OF BEECHAM INC. BRISTOL, TENN. 37620

EXECUTIVE OFFICES

615-764-5141

ABBREVIATED NEW DRUG APPLICATION

84-321

ANDA

May 16, 1974

Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Gentlemen:

Re: Probenecid and Colchicine Tablets
Abbreviated New Drug Application

Submitted herewith in triplicate is an Abbreviated New Drug Application for Probenecid and Colchicine Tablets.

The application is being submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, and §130.4(f) of the regulations promulgated thereunder; and as further provided for in the Federal Register of July 28, 1972, 37:15189, Desi 12383, entitled "Combination Preparation containing Probenecid and Colchicine."

Enclosed also is an Environmental Impact Analysis Report submitted as part of the Abbreviated New Drug Application.

We will appreciate the review of the enclosed submission at your earliest convenience.

Sincerely yours,

Lee Horning

Lee Horning
Regulatory Affairs Coordinator

Enclosures

Certified Mail
Return Receipt Requested

RECEIVED
MAY 20 1974
BUREAU OF DRUGS

Orig

Beecham laboratories

EXECUTIVE OFFICES 501 FIFTH STREET, BRISTOL, TENNESSEE 37620 615-764-5141

ANDA 84-321

March 9, 1982

Division of Generic Drug Monographs (HFD-530)
Office of Drug Monographs
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

WITHDRAWN

RE: ANDA 84-321
Probenecid with Colchicine Tablets

Gentlemen:

We voluntarily request withdrawal, without prejudice to any future filing, of our approved New Drug Application for Probenecid with Colchicine Tablets, ANDA 84-321.

The product has never been marketed.

Sincerely,

Lee Horning

Lee Horning
Regulatory Affairs Coordinator

LH/pjb

CC: Mr. L. P. Olon

CERTIFIED MAIL P271821364
RETURN RECEIPT REQUESTED

RECEIVED
MAR 11 1982
GENERIC DRUGS

Orig

Beecham
laboratories

EXECUTIVE OFFICES 501 FIFTH STREET, BRISTOL, TENNESSEE 37620 615-764-5141

April 3, 1981

WITHDRAWN

Marvin Seife, M.D., Director
Division of Generic Drug Monographs (HFD-530)
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Doctor Seife:

Re: NDA 84-321 - Probenecid with Colchicine Tablets

We are hereby requesting that our abbreviated new drug application for the above referenced product be withdrawn without prejudice to a subsequent filing. This action is being taken because of a lack of commercial interest in the drug at this time.

However, inasmuch as we plan to resubmit an NDA for this product should future circumstnaces so warrant, we cannot be said to have abandoned this drug or our application. Accordingly we consider the information submitted under NDA 84-321 to be trade secrets within the meaning of 21 CFR 20.61, and with respect to this information, hereby claim the exemption and protection from public disclosure provided by said section, as well as by 21 CFR 314.14.

We will greatly appreciate your consideration of this request and any subsequent action on your part which is consistent with its intent.

Yours sincerely,

Lawrence P. Olon
Director, Regulatory Affairs

LPO/dg

cc: Dr. D. R. Christian
Vice President, Scientific Affairs

RECEIVED
APR 6 1981

the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: July 11, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-11720 Filed 7-27-72;8:48 am]

[DESI 12177]

COMBINATION DRUG CONTAINING METHSCOPOLAMINE RESIN AND METHAQUALONE RESIN

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following anticholinergic-sedative drug:

Dimethacol Capsules containing methscopolamine resin and methaqualone resin (formerly called Akalon-T '5' Capsules and Akalon-T '10' Capsules); Strasenburgh Laboratories, Division Pennwalt Corp., 755 Jefferson Road, Rochester, N.Y. 14623 (NDA 12-177).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that this combination drug is possibly effective for its labeled indications.

B. Marketing status. Marketing of such drug with labeling which recommends or suggests its use for indications for which it has been classified as possibly effective may be continued for 6 months as described in paragraphs (d), (e), and (f) of the notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273).

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12177, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.
Original new-drug applications: Office of Scientific Evaluation (BD-100), Bureau of Drugs.
Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.
All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: July 11, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-11721 Filed 7-27-72;8:48 am]

[DESI 12383]

COMBINATION PREPARATION CONTAINING PROBENECID AND COLCHICINE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug:

ColBenemid Tablets containing probenecid and colchicine; Merck Sharp & Dohme, West Point, Pa. 19486 (NDA 12-383).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drug without approval.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that probenecid with colchicine is effective for the treatment of chronic gouty arthritis when complicated by frequent, recurrent, acute attacks of gout.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new-drug applications and abbreviated supplements to previously approved new-drug applications under conditions described herein.

1. *Form of drug.* Probenecid with colchicine preparations are in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The "Indications" section is as follows:

INDICATIONS

For the treatment of chronic gouty arthritis when complicated by frequent, recurrent acute attacks of gout.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), as follows:

a. For holders of "deemed approved" new-drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and an abbreviated supplement for updating information as described in paragraphs (a) (1) (i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new-drug application, the submission of an abbreviated new-drug application as described in paragraph (a) (3) (i) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12383, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.
Original abbreviated new-drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.
Request for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.
All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: July 11, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72-11723 Filed 7-27-72;8:48 am]

[DESI 5307]

PARENTERAL MERCURIAL DIURETICS

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following mercurial diuretics for parenteral use:

1. Cumertilin Injectable, containing mercumatilin; Endo Laboratories, Inc., subsidiary of E. I. du Pont de Nemours & Co., Inc., 1000 Stewart Avenue, Garden City, N.Y. 11530 (NDA 7-519).

2. Thiomerin Injection and Thiomerin Lyophilized Powder for Injection, containing sodium mercaptomerin; Wyeth Laboratories, Division American Home Products Corp., Post Office Box 8299, Philadelphia, Pa. 19101 (NDA 8-059).

3. Mercuhydrin Injection, containing meralluride; Lakeside Laboratories, Inc.,