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SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-21192 Filed 12-8-72;8:45 am]

### Food and Drug Administration

[FAP 3B2844]

### GULF OIL CORP.

### Notice of Filing of Petition for Food Additive

#### Correction

In F.R. Doc. 72-19956, appearing on page 24775, in the issue of Tuesday, November 21, 1972, the first line of the first paragraph should read "Pursuant to provisions of the Federal".

[DESI 12339]

### CERTAIN COMBINATION DRUGS FOR INHALATION

#### Drugs for Human Use; Drug Efficacy Study Implementation Follow-Up Notice

In an announcement (DESI 12339) published in the FEDERAL REGISTER of November 3, 1970 (35 F.R. 16951), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following products:

1. Bronkometer Aerosol containing isoetharine methanesulfonate, phenylephrine hydrochloride, and thenyldiamine hydrochloride; and

2. Bronkosol Solution (formerly named Bronkospray) containing isoetharine hydrochloride, phenylephrine hydrochloride, and thenyldiamine hydrochloride; Breon Laboratories, Inc., Subsidiary of Sterling Drug, Inc., 90 Park Avenue, New York, NY 10016 (NDA 12-339).

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application reviewed and are subject to this notice. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

The announcement stated that there is a lack of substantial evidence that these drugs are effective as fixed combinations for their labeled claims relating to bronchopulmonary disorders. Data providing substantial evidence of effectiveness have not been received pursuant to the announcement.

Subsequent to the notice of November 3, 1970, Breon Laboratories supple-

mented its new-drug application to revise the formulation and labeling of these products. The revised formulation eliminated the ingredient thenyldiamine hydrochloride. To reflect this change, these products are to be called Bronkometer-2 and Bronkosol-2. The revised formulations are as follows:

1. Bronkometer-2 containing isoetharine methanesulfonate and phenylephrine hydrochloride; and

2. Bronkosol-2 containing isoetharine hydrochloride and phenylephrine hydrochloride; Breon Laboratories, Inc., 90 Park Avenue, New York, NY 10016 (NDA 12-339).

The Commissioner finds it appropriate to announce his conclusions concerning these reformulated products as follows:

The Food and Drug Administration regards isoetharine methanesulfonate with phenylephrine hydrochloride and isoetharine hydrochloride with phenylephrine hydrochloride as less than effective (probably effective) for the acute relief of bronchial asthma and other conditions in which bronchospasm is a complicating factor, such as chronic bronchitis or emphysema.

Any data submitted in response to this notice to support indications for which a drug is classified as other than effective must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12 (a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

Communications forwarded in response to this notice should be identified with the reference number DESI 12339, 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.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-80), 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 the Administrative Procedure Act (5 U.S.C. 554), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: November 30, 1972.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.72-21310 Filed 12-8-72;8:48 am]

[DESI 7337]

### COMBINATION CONTAINING OXYCODONE HYDROCHLORIDE, OXYCODONE TEREPHTHALATE, ASPIRIN, CAFFEINE, AND PHENACETIN FOR ORAL USE

#### Drugs for Human Use; Drug Efficacy Study Implementation Classification Amended

The Food and Drug Administration published a notice in the FEDERAL REGISTER of April 20, 1972 (37 F.R. 7827), regarding the efficacy of Percodan tablets containing oxycodone hydrochloride, oxycodone terephthalate, homatropine terephthalate, aspirin, phenacetin, and caffeine; Endo Laboratories, Inc., 1000 Stewart Ave., Garden City, Long Island, NY 11530 (NDA 7-337).

Other drugs were also included in the notice of April 20, 1972. With respect to those drugs, the conclusions and requirements described in that notice are unchanged and they will be the subject of a future follow-up notice.

The notice stated that Percodan tablets were regarded as possibly effective for moderate to moderately severe pain, and lacking substantial evidence of effectiveness as a fixed combination for antipyresis. The evaluation of possibly effective was based upon the lack of justification for the inclusion of homatropine terephthalate in the formulation and certain deficiencies in the labeling.

Subsequent to the notice of April 20, 1972, Endo Laboratories submitted a supplement to NDA 7-337 proposing revised labeling and reformulation of Percodan tablets and Percodan-Demi tablets (not submitted to the Academy for review and not included in the April 20, 1972 notice). The revised formulation eliminated homatropine terephthalate. The supplement was approved July 11, 1972.

Since the reformulation and relabeling, resulting in approval of the preparations, were a direct result of the Drug Efficacy Study Implementation, the Commissioner of Food and Drugs finds it appropriate to set forth below, his evaluation and requirements concerning oral tablets containing oxycodone hydrochloride, oxycodone terephthalate, aspirin, phenacetin, and caffeine.

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 concerning Percodan (prior to reformulation to delete homatropine terephthalate), as well as other available evidence, and concludes that combination drugs containing oxycodone hydrochloride, oxycodone terephthalate, aspirin, caffeine, and phenacetin are effective for the relief of moderate to moderately severe pain.

**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.* Oxycodone hydrochloride, oxycodone terephthalate, aspirin, caffeine and phenacetin combination preparations are in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The labels bear 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" are as follows:

**INDICATIONS**

For relief of moderate to moderately severe pain.

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 or 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 7337, 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.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-66),  
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: December 6, 1972.

SAM D. FINE,  
Associate Commissioner for  
Compliance.

[FR Doc.72-21308 Filed 12-8-72;8:48 am]

[DESI 13334; Docket No. FDC-D-569;  
NDA 13-334]

**MERCK SHARP AND DOHME**

**Dexamethasone Sodium Phosphate and Lidocaine Hydrochloride Injection, Dilute; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application**

In an announcement (DESI 13334) published in the FEDERAL REGISTER of September 23, 1970 (35 F.R. 14800), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following drug:

That part of NDA 13-334 pertaining to Decadron Phosphate with Xylocaine Injection, Dilute containing dexamethasone sodium phosphate 1 mg./ml. and lidocaine hydrochloride 5 mg./ml.; Merck Sharp and Dohme, Division of Merck and Co. Inc., West Point, Pa. 19486.

The announcement stated there is a lack of substantial evidence that this fixed combination drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug application for this drug.

Interested persons were invited to submit pertinent data bearing on the proposal within 30 days following publication of the announcement. No data providing substantial evidence of effectiveness have been received.

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of pertinent parts of the listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug(s) will have all the effects purported or represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new

drug application(s) reviewed. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

Within 30 days after publication hereof in the FEDERAL REGISTER the applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election within said 30 days will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of pertinent parts of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) for the labeling claims involved, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the