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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.