

FLAG OF REGISTRY AND NAME OF SHIP		Gross tonnage
a. Since last report:		
British (5 ships)	-----	58,323
London Glory (Tanker)	-----	10,061
London Majesty (Tanker)	-----	12,132
London Pride (Tanker)	-----	10,776
London Splendour (Tanker)	-----	16,195
Maple Hill	-----	7,139
Greek (2 ships)		32,969
Proteus (Tanker)	-----	16,718
Sirlus (Tanker)	-----	16,241
Norwegian (1 ship):		
Lovdal (Tanker)	-----	12,784

b. Previous reports:

Flag of registry:	Number of ships
British	19
Danish	1
French	1
German (West)	1
Greek	16
Italian	5
Japanese	1
Norwegian	2
Spanish	1

Sec. 3: The ships listed in sections 1 and 2 have made the following number of trips to Cuba since January 1, 1963, based on information received through October 19, 1964:

Flag of registry	Number of trips												Total
	1964												
	1963	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.		
British	133	36	7	21	20	18	19	18	17	12	2	242	
Lebanese	64	6	4	13	8	8	10	8	9	9		139	
Greek	99	1	5	3	6	1	4	2	2			120	
Italian	16	1			1	2	1	1	1			22	
Norwegian	14	2	1		3	2	2	2	2			21	
Spanish	8		3			2	1		1	2	2	23	
Norwegian	9		2				3		2			21	
Yugoslav	12	1	1	1	1		2	2				13	
French	3				1		2					5	
Swedish	8						1		1			4	
Finnish	1								1			2	
Kuwait								1				1	
Cyprus												1	
Danish	1											1	
German (West)	1											1	
Japanese										1		1	
Netherlands											4	689	
Sub Total	370	26	23	39	37	41	41	40	31	4		30	
Polish	18	1	3	1	2	2	1		2			719	
Grand Total	388	27	26	40	39	37	43	42	40	13	4		

NOTE: Trip totals in this section exceed ship totals in Sections 1 and 2 because some of the ships made more than one trip to Cuba.

By order of the Deputy Maritime Administrator.
Dated: October 22, 1964.

JAMES S. DAWSON, Jr.,
Secretary.

[F.R. Doc. 64-10981; Filed Oct. 27, 1964; 3:50 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. D-82; NDA 11-331]

BARIATRIC CORP.

Neo-Barine; Notice of Withdrawal of Approval of New-Drug Application

On May 21, 1964, the Commissioner of Food and Drugs issued a Notice of Opportunity for Hearing on his proposal to issue an order withdrawing approval of New-Drug Application No. 11-331 and all amendments and supplements thereto held by the Bariatric Corporation, Coral Gables, Fla., for the drug Neo-Barine, on the following grounds:

1. New evidence of clinical experience, not contained in such application or not available until after such application was approved, evaluated together with the evidence available when the application was approved, shows that the drug is not

shown to be safe for use under the conditions of use upon the basis of which the application was approved, in that clinical experience shows that the use of Neo-Barine produces the same physiological effects as the administration of thyroid and that its use has been associated with undesirable thyrotoxic side effects.

2. New-Drug Application No. 11-331 contains untrue statements of material fact, in that there are differences in the conditions of use prescribed, recommended, or suggested by the applicant for Neo-Barine from the conditions of such use stated in the application and differences in the labeling from the specimens contained in the application: To wit, that there is no increase in calcium, phosphorus, chloride, or nitrogen excretion with use of Neo-Barine; that blood protein and 17 ketosteroids remain within normal limits; that urinary ketones remain negative; that elevated blood cholesterol levels significantly decrease; that it is not an anorexic agent but an anti-adipogenic antago-

nistic to the storage of fat which mediates its action through adipose tissue; that it reduces food requirements resulting in a spontaneous reduction of food consumed without drugs to curb appetite; that weight increase does not take place after withdrawal of Neo-Barine; that energy requirements are satisfied on Neo-Barine; that side reactions will disappear spontaneously within a few days without change of dosage, though it may be necessary, in some cases, to suspend medication for a few days; that medium-acting barbiturates, such as pentobarbital, control tremors; that an occasional patient exhibits muscle weakness, especially of the legs, at the start of treatment which is controlled by 7 1/2 grains of potassium chloride daily for a few weeks; that diuretics may be employed for patients exhibiting a tendency to fluid retention; that it is not contraindicated in hypertension; that it may result in elevated blood sugar; that it is contraindicated in the presence of pregnancy or a previous history of iodism; that children over 13 years old tolerate it at the same levels as given to adults; that it contains 1.08 percent thyroxin; that it may be administered to patients having diabetes, colitis, or hypertension; and that it may produce a marked drop in blood pressure.

The Notice of Opportunity was sent by certified mail and received by the Bariatric Corporation on May 26, 1964. It was published in the FEDERAL REGISTER on May 27, 1964 (29 F.R. 6963).

On June 24, 1964, the Bariatric Corporation, pursuant to the provisions of 21 CFR Part 130, elected to avail itself of the opportunity for hearing afforded by the Commissioner's notice.

Pursuant to the request for hearing, on June 29, 1964, John L. Harvey, Deputy Commissioner of Food and Drugs, designated William E. Brennan as Hearing Examiner to conduct the hearing on the Commissioner's proposal to withdraw approval for NDA 11-331 and all amendments and supplements thereto for Neo-Barine.

On August 3, 1964, the prehearing conference was held, and at the request of the Bariatric Corporation a postponement of the hearing from August 10, 1964, date was granted. As a further result of the prehearing conference a prehearing order was entered by the Examiner on August 7, 1964, specifying, among other matters, the issues to be resolved at the hearing.

On August 24, 1964, the hearing commenced with the presentation of the Food and Drug Administration's evidence. This hearing continued from time to time until September 21, 1964, when the Bariatric Corporation requested a continuance of the hearing to October 6, 1964. This continuance was granted over objection of Government counsel by the hearing examiner on the agreement of the Bariatric Corporation to cease distribution of Neo-Barine as of September 21, 1964. The purpose of the continuance was, as stated by counsel for Bariatric Corporation, to provide counsel with time in which to consult

with officers of the Corporation to determine which of two alternative courses of action to follow in light of the progress of the hearing to date. The alternatives were (1) to continue the hearing in the manner provided by statute; or (2) to withdraw the Company's request for hearing with the result that the Commissioner would withdraw approval of the New-Drug Application.

By letter dated October 1, 1964, to the hearing examiner, and received October 5, 1964, the Bariatric Corporation withdrew its election to avail itself of the opportunity for a public hearing on the proposed withdrawal of the New-Drug Application No. 11-331 for Neo-Barine.

Therefore, the Bariatria Corporation, Coral Gables, Florida, holder of the New-Drug Application No. 11-331, having availed itself of an opportunity for a public hearing pursuant to the Notice of Opportunity for Hearing published May 27, 1964, and having proceeded to hearing on August 24, 1964, and then withdrawing its request for hearing on October 1, 1964, and no other party having elected or appeared:

The Commissioner of Food and Drugs, by virtue of the authority vested in the Secretary of Health, Education, and Welfare by the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505 (e), 52 Stat. 1053; 21 U.S.C. 355(e)) and delegated to the Commissioner by the Secretary (21 CFR 2.90; 29 FR 471) finds that, on the basis of new evidence of clinical experience, not available until after the New-Drug Application for Neo-Barine was approved, evaluated together with the evidence available when the application was approved, the drug Neo-Barine produces the same physiological effects as the administration of thyroid and its clinical use causes undesirable thyrotoxic side effects, and that therefore Neo-Barine is not shown to be safe for use under the conditions for use upon the basis of which the application was approved.

The Commissioner further finds that New-Drug Application 11-331 for Neo-Barine contains untrue statements of material fact, in that there are differences in the conditions of use prescribed, recommended, or suggested by the Bariatric Corporation from the conditions of use stated in the application. Such differences consist of claims and representations about the drug Neo-Barine that have never been submitted as part of the New-Drug Application 11-331 for Neo-Barine and about which Bariatric Corporation has never submitted supporting data.

Therefore, on the foregoing findings of fact, the approval of New-Drug Application 11-331, applying to Neo-Barine, is withdrawn, effective on the date of signature of this document.

Dated: October 22, 1964.

GRO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 64-10959; Filed, Oct. 27, 1964;
8:48 a.m.]

CIVIL AERONAUTICS BOARD

[Docket No. 15353; Order E-21430]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Regarding North Atlantic Excursion Fares

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 23d day of October 1964.

Agreement adopted by Joint Conference 1-2 of the International Air Transport Association relating to North Atlantic excursion fares; Docket No. 15353, Agreement C.A.B. 17993.

There has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, an agreement between various air carriers, foreign air carriers and other carriers, embodied in the resolutions of Joint Conference 1-2 of the International Air Transport Association (IATA). The agreement, which has been assigned the above-designated C.A.B. agreement number, was adopted at meetings in Athens and carries an early effectiveness date of October 26, 1964.

The agreement will permit the application of 14-21 day round-trip excursion travel on the North Atlantic during the winter period November 6 through February 14, which travel is now prohibited during this period by the terms of the existing agreement. The fares for travel have been set at a level \$35 higher than the current excursion fares, producing a New York-London fare of \$335. However, existing fares to Spain will be maintained. Existing restrictions against travel on weekends will be continued during this period, except with respect to transportation purchased, and for which firm reservations were made, prior to October 15, 1964, for travel to Spain and Portugal.

The Board has urged the carriers to offer reduced fares in the winter months when traffic is at a minimum and ample capacity exists to carry substantially increased traffic. The Board stressed this view, particularly since the revised fare structure that became effective in April of this year did not include excursion fares as in preceding years and, this, would result in an increase for many passengers traveling in the winter. The New York-London fare of \$335 provides a reduction of \$64 from the normal round-trip fare of \$399 and is lower than the \$350 excursion fare of last year. The Board would have favored still a lower fare as a means of adequately testing the traffic generating effects of a rock-bottom price during the winter. However, we believe that the proposed fare, the lowest jet fare ever offered in the winter, will afford some opportunity to test the generating effects of reduced winter fares.

The Board acting pursuant to sections 102, 204(a) and 412 of the Act, does not find the above-described agreement, in-

corporated in IATA Resolution JT12(33) 080c, to be adverse to the public interest or in violation of the Act.

Accordingly, it is ordered, That, Agreement C.A.B. 17993 is approved.

Any air carrier party to the agreement, or any interested person, may, within 15 days from the date of service of this order, submit statements in writing containing reasons deemed appropriate, together with supporting data, in support of or in opposition to the Board's action herein. An original and nineteen copies of the statements should be filed with the Board's Docket Section. The Board may upon consideration of any such statements filed, modify or rescind its action herein by subsequent order.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

[SEAL] HAROLD R. SANDERSON,
Secretary.

[F.R. Doc. 64-10977; Filed, Oct. 27, 1964;
8:49 a.m.]

[Docket No. 15353; Order E-21433]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Regarding Interline Arrangements With Non-IATA Carriers

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 23d day of October 1964.

Agreement adopted by the traffic conferences of the International Air Transport Association relating to interline arrangements with non-IATA carrier Docket No. 15353, Agreement C.A.B. 17845 R-65 through R-88.

There has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, an agreement between various air carriers, foreign air carriers, and other carriers embodied in the resolutions of a Traffic Conference of the International Air Transport Association (IATA) adopted at meetings held in Tokyo, June 1964. The agreement, which has been assigned the above-designated C.A.B. Agreement number, amends IATA Resolutions 450 (Form of Interline Traffic Agreement) and 451 (Interline Agreements with Non-IATA Carriers).

The amendment to Resolution 8 which sets forth the rules governing interline arrangements of a bilateral nature with non-IATA carriers, extends Traffic Conference 1 and all of Traffic Conference 3 existing provisions applicable in the Middle East, Libya, Tunisia and India which require adherence of non-IATA carriers to IATA rules and practices. In addition, the revisions provide for the inspection by the IATA enforcement officer of the non-IATA carrier's records and accounts and in event of a finding that the non-IATA carrier has failed to adhere to the IATA fares, rates, charges, rules, or practices.