CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020181

APPROVAL LETTER

NDA 20-181

JAN 13 1998

Abbott Laboratories
Hospital Products Division
Attention: Mr. Thomas P. Sampogna
Manager, Regulatory Affairs
D-389 Bldg. AP30
200 Abbott Park Road
ABBOTT PARK, ILLINOIS 60064-3500

Dear Mr. Sampogna:

Please refer to your new drug application dated April 10, 1991, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Liposyn III® 30% (intravenous fat emulsion), Pharmacy Bulk Package.

We acknowledge receipt of your major amendment dated July 24, 1997, and received on July 25, 1997, in response to our not approvable letter dated March 24, 1997. We also acknowledge receipt of your submissions dated October 22, 24, and 27, November 4, 5, and 11, and December 19 and 23, 1997.

The regulatory due date for this application is January 21, 1998.

This new drug application provides for Liposyn III® in a new 30% strength and in a Pharmacy Bulk Package to be used in a pharmacy admixture program for the preparation of 3-in-1 or total nutrient admixture (TNAs) as a source of calories for patients requiring parenteral nutrition and of essential fatty acids for extended parenteral nutrition.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated December 23, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on December 23, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-181. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions

1.

2.

3.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition we request under CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Steve McCort, Project Manager, at (301) 827-6415.

Sincerely yours,

/S/ 1-13-98

Solómon Sobel, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-181
HFD-510/Div. files
HFD-510/CSO/S.McCort
HFD-510/SSobel/GTroendle/EColman/SKoch/DWu/RSteigerwalt/E Galliers
HFD-805/NSweeny/PCooney
HFD-870/CJones/HAhn
HFD-002/ORM (with labeling)
HFD-102/Office Director
HFD-101/L.Carter
HFD-820/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFI-20/Press Office (with labeling)

Drafted by: smm/January 2, 1998/n20181.app
Initialed by: edited: Jan. 13, 1998
final:

APPROVAL (AP)
WITH PHASE 4 COMMITMENTS

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.