

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020181**

**MICROBIOLOGY REVIEW(S)**

REVIEW FOR HFD-510

OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review # 2 of NDA 20-181  
July 8, 1996

A. 1. APPLICATION NUMBER: NDA 20-181

APPEARS THIS WAY  
ON ORIGINAL

APPLICANT: Abbott Laboratories  
Hospital Products Division  
Abbott Park, IL 60064-3500

2. PRODUCT NAME: Liposyn III 30% Pharmacy Bulk Package

3. DOSAGE FORM: Sterile fat emulsion in 500 ml and 1000 ml  
Pharmacy bulk package.

4. METHOD OF STERILIZATION:

5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:  
Source of calories in parenteral nutrition.

6. DRUG PRIORITY CLASSIFICATION: 3C

APPEARS THIS WAY  
ON ORIGINAL

B. 1. DATE OF INITIAL SUBMISSION: April 10, 1991

2. DATE OF AMENDMENT: May 28, 1996

5. ASSIGNED FOR REVIEW: June 11, 1996

C. REMARKS:

Microbiologist's Review #1 (dated Oct. 31, 1991) yielded five questions that were subsequently faxed to the applicant on Dec. 3, 1991. The applicant's response(s) to these questions/issues are provided below, and follow the microbiologist's questions provided in italics.

APPEARS THIS WAY  
ON ORIGINAL

/S/



**D. CONCLUSIONS:**

The application is recommended for approval for issues concerning sterility assurance. We acknowledge that Abbott Laboratories has withdrawn the 1000 ml Liposyn III 30 % product size from NDA 20-181.

**APPEARS THIS WAY  
ON ORIGINAL**

**/S/**  
Neal Sweeney, Ph.D.

7/8/96  
7/15/96

**/S/**

cc:

- Original NDA 20-181
- HFD-510/ Division File
- HFD-510/CSO/C. Kish
- HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, July 8, 1996  
R/D initialed by P. Cooney July 8, 1996

**APPEARS THIS WAY  
ON ORIGINAL**

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ON ORIGINAL**

MCCORT

OCT 31 1991

Division of Medical Imaging, Surgical and Dental Drug Products  
Microbiologist's Review No. 1  
October 31, 1991

- A. 1. Application Number: NDA 20-181
- Applicant: Abbott Laboratories  
Hospital Products Division  
Abbott Park, IL 60064-3500
2. Product Name: Liposyn III 30%, Pharmacy Bulk Package
3. Dosage Form: Sterile Fat Emulsion in 500 ml and 1000 ml  
Pharmacy Bulk Package
4. Method of Sterilization:
5. Pharmacological Category and/or Principle Indication:  
Source of calories in parenteral nutrition.
6. Drug Priority Classification: 3C
- B. 1. Initial Submission: April 10, 1991
2. Amendments: N/A

C. Remarks:

The subject drug product is to be supplied in 500 ml and 1000 ml containers and will be manufactured at the North Chicago facility as follows:

<u>Container Size</u>	<u>Mfg. Site</u>	<u>Sterilization Process</u>
1000 ml	N. Chicago	
500 ml	N. Chicago	

The manufacturing procedures relative to sterilization

D. **Conclusions:**

the application is not recommended for approval on the basis of sterility assurance.

**/S/**

12/31/41  
Peter H. Cooney, PhD  
Supervisory Microbiologist **/S/** 11/29/41

**APPEARS THIS WAY  
ON ORIGINAL**

cc: NDA 20-181  
HFD-160/Cooney/Koch/Wilson/Kenealy/McCord

**APPEARS THIS WAY  
ON ORIGINAL**