

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 20849**

**MICROBIOLOGY REVIEW(S)**

McCourt  
510

MAR 18 1998

**REVIEW FOR HFD-510  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-849  
March 12, 1998**

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**A. 1. NDA 20-849**

**APPLICANT:**

Baxter Healthcare Corporation  
Route 120 & Wilson Road  
Round Lake, Illinois 60073-0490

**2. PRODUCT NAME:**

20% ProSol™

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**3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile sulfite-free amino acids solution in (PL 146) flexible (500, 1000, and 2000 mL) plastic containers (pharmacy bulk package)  
For intravenous injection.

**4. METHODS OF STERILIZATION:**

**5. PHARMACOLOGICAL CATEGORY and/or PRINCIPAL INDICATION:**

The drug products are indicated as a caloric component in a parenteral nutrition regimen and as a protein source to off-set nitrogen loss.

**6. DRUG PRIORITY CLASSIFICATION:** 3S

**B. 1. DATE OF INITIAL SUBMISSION:**

August 25, 1997

**2. RELATED DOCUMENT:**

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**3. DATE OF CONSULT:**

September 2, 1997

**4. ASSIGNED FOR REVIEW:**

September 16, 1997

**C. REMARKS:** The drug product consists of drug substances and a container already approved in other Baxter amino acid products. Because of its higher concentration of amino acids, the drug product can supply an amino acid dose equivalent to lower concentration products but in a smaller volume.

**D. CONCLUSIONS:** The application is recommended for approval for microbiology issues concerning sterility assurance.

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Neal Sweeney, Ph.D.  
*/S/* 3/18/98

cc: Original NDA 20-849  
HFD-510/Division Files  
HFD-510/S. McCort  
HFD-805/Consult File/Sweeney

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Drafted by: N. Sweeney, March 12, 1998  
R/D initialed by P. Cooney, March 12, 1998