DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-321/S-008

Baxter Healthcare Corporation
Attention: Lisa M. Skeens, Ph.D.
Vice President, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085-6730

Dear Dr. Skeens:

Please refer to your supplemental new drug application dated November 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Extraneal (icodextrin) Peritoneal Dialysis Solution 7.5%.

We also acknowledge receipt of your submissions dated February 26 and March 26, 2004, and March 18, 2005. Your March 18, 2005 submission constituted a complete response to our March 26, 2004 action letter.

This supplemental new drug application provides for the use of the Lineo Connector as an associated component of the UltraBag continuous ambulatory peritoneal dialysis (CAPD) container-closure system and a comparability protocol for the use of the connector with additional fill sizes. The labeling has been revised as follows:

1. The following paragraph has been added to the **DESCRIPTION** section:

   Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration dating period, e.g. di 2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

2. Under **How Supplied**, the following container descriptions have been added:

ULTRABAG with LINEO	2.0 L	NDC 0941-0679-72
ULTRABAG with LINEO	2.5 L	NDC 0941-0679-73

3. The description of trademarks has been changed from:

   BAXTER, EXTRANEAL, ULTRABAG, and AMBU-FLEX are trademarks of Baxter International, Inc.

   To:

   BAXTER, EXTRANEAL, ULTRABAG, AMBU-FLEX, and LINEO are trademarks of Baxter International, Inc.
   LINEO Connector Pats. Pending

4. The copyright description has been changed from:

To:

The container labels of the new products using the LINEO connectors have been revised as follows:

1. The product name **EXTRANEAL** has been changed to all capital letters.

2. "**UltraBag** CONTAINER" has been changed to "**UltraBag** CONTAINER WITH LINEO CONNECTOR"

3. The following text has been added:

   THE LINEO CONNECTOR CONTAINS POVIDONE IODINE

4. The trademark description has been changed from:

   BAXTER EXTRANEAL ULTRABAG AND **PL146** ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

   To:

   BAXTER EXTRANEAL ULTRABAG LINEO AND **PL146** ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

5. The following patent information has been added:

   LINEO CONNECTOR PATS PENDING

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on March 18, 2005.

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:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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