DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-884/S007, S008
NDA 20-855

Baxter Healthcare Corporation
Route 120 and Wilson Road; RLT-10
Round Lake, IL 60073-0490

Attention: Marcia Marconi
V.P. Regulatory Affairs
Medication Delivery Division

Dear Ms. Marconi:

Please refer to your supplemental new drug applications dated September 29, 2000, received October 2, 2000 (S007) and November 20, 2002, received November 21, 2002 (S008), submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Mesnex (mesna) Injection and Tablets. We also refer to your final printed labeling submitted July 19, 2002 in response to our March 21, 2002 approval letter for Mesnex (mesna) Tablets.

These "Changes Being Effected" supplemental new drug applications provide for the following:

S007 the addition of injection site reactions to the ADVERSE REACTIONS section and several editorial revisions

S008 final printed labeling combining the injection with the tablets

We note that S007 has been superseded by S008; therefore, we will not review this supplemental application (S007), but it will be retained in your file.

We completed our review of supplemental new drug application S008 and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 20, 2002.

We have also reviewed the labeling that you submitted July 19, 2002 in accordance with our March 21, 2002 approval letter for Mesnex Tablets and we find it acceptable. We note these two FPLs are identical except for the addition of a patient package insert for the tablet labeling.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Sheila Ryan, Regulatory Project Manager, at (301) 594-5771.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology 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/

Richard Pazdur

1/30/03 02:42:36 PM