

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

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Division of Pharmacy - 90

May 26, 1998

Docket Management Branch (HFA-305)
Food and Drugs Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20855

RE: Docket No. 98N-0182

Dear Sirs:

Please find enclosed information to nominate three candidate bulk drug substances for consideration for inclusion in the list for pharmacy compounding of materials that do not have USP or NF monographs and are not components of approved drugs. This is a new list that is being assembled in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

The three candidate bulk drug substances at this time are:

1. Dinitrochlorobenzene (DNCB)
2. Sodium butyrate
3. Ferric subsulfate

I have also forwarded this material to USP for their use in participating in this process.

If there is anything further I need to do, please let me know. (713-792-2870).

Sincerely yours,



Lawrence A. Trissel, FASHP
Director, Clinical Pharmaceutics Research Program

98N-0182

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