

Central File

NOV 2 1979

St. Marys Hospital
ATTN: Sister Priscilla Grimes
Administrator
2323 North Lake Drive
Milwaukee, WI 53211

License No. 48-01828-01

Gentlemen:

During a recent inspection of Nuclear Pharmacy, Inc. of Milwaukee, it was learned that a number of hospitals in the Milwaukee area including St. Marys Hospital received unit doses of Xe-133 that were prepared from bulk material that was labeled, "Pharmaceutically Unrefined. Not tested for sterility or freedom from pyrogens. Not for human use in present form." This matter was discussed in a telephone conversation on October 5, 1978, between Dr. Ruetz of your staff and C. J. Paperiello of our staff. At that time you were told that you would receive a list of shipments sent to you which were prepared from this material labeled "Pharmaceutically Unrefined." This information is enclosed.

About half the unit dose shipments made between July 11, 1977, and January 17, 1979, were prepared in such a fashion. The remainder were prepared from bulk material obtained from FDA approved suppliers.

To our knowledge, no adverse reactions have been noted. This information is being supplied to aid you in making medical decisions if needed.

If you have any questions on this matter do not hesitate to call Carl J. Paperiello of this office at (312) 932-2500.

Sincerely,

James G. Keppler
Director

Enclosure: As stated

cc w/encl:
Central Files
Reproduction Unit NRC 20b
PDR
NSIC

bcc w/encl:
J. H. Sniezek, IE:HQ
ELD
OIA

RIII
[Signature]
Paperiello/km Davis

RIII
[Signature]
Nopelius
11/1/79

RIII
[Signature]
Keppler

10/30/79

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UNIT DOSE RECEIVED BY ST. MARYS HOSPITAL

<u>Date Distributed</u>	<u>Activity (mCi)</u>	<u>Prescription No.</u>
3/29/78	11.0	13062
3/31/78	9	13161
3/31/78	11	13162
3/29/78	12	13063
3/15/78	10.50	12367
3/15/78	13.50	12368
3/15/78	11.50	12369
3/15/78	10	12370
3/15/78	10.5	12371
2/16/78	12	10862
2/16/78	11.0	10863
2/17/78	10.4	10933
2/17/78	11.70	10934
2/17/78	11.70	10945
2/17/78	13.70	10946
2/3/78	10	10135
2/3/78	10.6	10136
1/16/78	9.50	08879
1/16/78	10.1	08880
1/16/78	8.20	08881
1/17/78	10.3	08962
1/17/78	10.2	08963
1/17/78	10.70	08964
1/18/78	10.60	09040
1/18/78	9.50	09041
1/18/78	9.80	09042
1/19/78	12.00	09138
1/19/78	10.80	09139
1/19/78	10.0	09140
1/19/78	8.50	09141
1/19/78	9.50	09142
1/3/78	15.0	08114
12/29/78	12.50	07930
12/29/78	16.00	07931
12/29/78	13.80	07932
12/30/77	11.5	07988
12/30/77	12.0	07989
12/30/77	13.5	07990
12/30/77	15.0	07991
1/2/78	10.60	08032
12/13/77	12.00	07078
12/13/77	14.00	07079
12/16/77	11.6	07291
12/16/77	11.3	07292
12/16/77	10.0	07293
12/16/77	11.4	07294
12/18/78	13.70	30179
2/19/78	11.50	30208
2/19/78	12.30	30209
2/19/78	12.00	30293
2/19/78	12.60	30294
2/19/78	11.00	30295