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February 24, 1987 0487-41

United States Nuclear Regulatory Commission Region I Nuclear Materials Cafety Section B Division of Radiation Safety & Safeguards 631 Park Avenue King of Prussia, Pennsylvania 19406

187 MAR -4 A8:50

Gentlemen:

REFERENCE: License No. 37-16707-02G Docket No. 030-12125

ICN Micromedic Systems, Inc., is submitting the proposed changes to the labeling of tracers included in our in vitro diagnostic kits.

The label will no longer be a printed product-specific label. The "generic" label has been developed, with the pertinent information for each product being computer printed. The information printed will be the same as those submitted on our license renewal dated September 15, 1986.

I have provided the generic tracer label and examples of two tracers computer printed for Digoxin and TSH.

If you have any questions, please contact me at (215)443-3012.

Sincerely,

Deborah L. Lindemuth

Manager, Regulatory Affairs

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Enclosures

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## SAMPLE TRACER LABELS

Total Activity. < 10 μCi



CAUTION

ICN MICROMEDIC SYSTEMS
For in vitro diagnostic use. Store at 4°C.
See package insert for directions.

DIGUXIN DO440-R5 Total Activity < 10µCl 125-I TRACER

Contains 25mL of buffer with labeled Digoxin and O.1% NaNa

TSH DQ940-R3 Total Activity: < 10 LG

125-I TRACER

Contains 11mL of labeled rabbit anti-TSH and 0.1% NaNa

LOT XXXX EXP XXXX XX RADIOACTIVE

ICN MICROM-SDIC SAS REMS
HORSHAM, PA 19044

For in vitro diagnostic use. Store at 3°C.
See package insert sur directions.