

File

June 24, 1987

Nuclear Diagnostics, Inc.
Sterling Biochemical, Inc.
ATTN: James B. Smart, Ph.D.
Regulatory Affairs Officer
575 Robbins Drive
Troy, MI 48083

Gentlemen:

We have reviewed your letter and application dated June 10, 1987, which provided additional information regarding the renewal of License No. 21-14161-01G. Please provide the following information:

1. Our review of the NOI labels submitted show that they do not meet the wording requirements of Section 32.71(c)(2) in that they do not contain the statement "Not for Internal or External Use in Humans or Animals." The labels must be modified to meet the regulations. Please provide a statement that the labels will be changed to meet the regulations and provide the date this will be accomplished.
2. In addition, please submit samples of the reagent bottle labels and brochures for the kits manufactured by Farnos Diagnostica so that we may be assured that they meet the provisions of Section 32.71 of 10 CFR Part 32 before we authorize their distribution to general licensees.
3. Regarding kits manufactured by other companies indicate whether or not you alter labels or brochures. If so, please submit the new or modified labels and brochures.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 82548.

Sincerely,

Evelyn R. Matson
Materials Licensing Section

8804210510 870929
REG3 LIC30
21-14161-01G PDR

RIII
ERM
Matson/nma
6/25/87

RIII
ERM for
Mallett
6/25/87

CONVERSATION RECORD

TIME 300

DATE 5/13/87

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

Nuclear Diagnostics

SUBJECT

ROUTING

NAME/SYMBOL

INT

SUMMARY

Pursuant to letter dated 5/8/87 NRC will extend response time by 30 days.

Response due 6/15/87

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

[Signature]

5/13/87

ACTION TAKEN

SIGNATURE

TITLE

DATE