

April 8, 1997

Docket No. 030-30915

License No. 37-28318-02

Michael A. Christie, Ph.D.
General Manager
Zynaxis, Incorporated
371 Phoenixville Pike
Malvern, Pennsylvania 19355

SUBJECT: INSPECTION NO. 030-30915/97-001

Dear Dr. Christie:

On March 20, 1997, Sheri A. Arredondo of this office conducted a safety inspection at the above location of activities authorized by the above listed NRC license. Ms. Arredondo was accompanied by me. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you, at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in

RETURN ORIGINAL TO
REGION I

OFFICIAL RECORD COPY

9704150042 770408
PDR ADOCK 03030915
C PDR



M. A. Christie, Ph.D.
Zynaxis, Incorporated

-2-

Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

ORIGINAL SIGNED BY:

Duncan White

for

Jenny M. Johansen, Chief
Nuclear Materials Safety Branch No. 3
Division of Nuclear Materials Safety

Docket No.: 030-30915
License No.: 37-28318-02

Enclosure:
Notice of Violation

cc w/enclosure:
Wilhelmus C. Kokke, Ph D.,
Radiation Safety Officer

Commonwealth of Pennsylvania

M. A. Christie, Ph.D.
Zynaxis, Incorporated

-3-

Distribution: w/encl
PUBLIC

Nuclear Safety Information Center (NSIC)
Region I Docket Room (w/concurrences)
D. J. Holody, RI

DOCUMENT NAME: R:\WPS\MLDL\L3728318.02

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	Arredondo <i>A</i>		Johansen <i>JW</i>				
DATE	04/02/97		04/8/97		04/ /97		04/ /97

OFFICIAL RECORD COPY