

MAR 9 1994

Docket Nos. 030-30914  
030-30915

License Nos. 37-28318-01  
37-28318-02

Zynaxis Cells Science, Inc.  
ATTN: Katharine A. Muirhead, Ph.D.  
Senior Vice President  
Pharmaceutical Division  
371 Phoenixville Pike  
Malvern, Pennsylvania 19355

Dear Dr. Muirhead:

SUBJECT: ROUTINE INSPECTION NOS. 030-30914/94-001 AND 030-30915/94-001

On November 30, 1993 and December 1, 1993, Judith A. Joustra of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC licenses. 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. In addition, our inspection examined the activities covered in your correspondence dated January 5, 1994 and January 31, 1994. The findings of the inspection were discussed with you and Michael R. McDevitt, Ph.D. of your staff at the conclusion of the inspection. This also refers to the telephone conversations between Michael R. McDevitt, Ph.D. and Kathleen Dolce.

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 as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

Item A in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities and documented in a Notice of Violation enclosed with our letter dated September 5, 1989. From this inspection, it appears that your corrective actions were not effective since this item has recurred. Recurrent and uncorrected violations are given additional weight in the consideration and selection of appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

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Please use the enclosed self-addressed green envelope when you submit your copy to the Regional Administrator, Region I. This will assist us in the timely processing of your response. 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. The responses directed by this letter and the accompanying 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:  
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief  
Research and Development Section  
Division of Radiation Safety  
and Safeguards

Enclosure:  
Appendix A, Notice of Violation

cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Pennsylvania  
Michael R. McDevitt, Radiation Safety Officer

Zynaxis Cells Science, Inc.

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bcc:  
Region I Docket Room (w/concurrences)  
D.J. Holody, RI

DRSS:RI  
Dolce/EC  
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