

JUN 1 1994

Docket No. 030-19953  
EA No. 92-224  
MN No. 94-68

License No. 20-20592-01

Creative Biomolecules, Inc.  
ATTN: William F. Kusmik, Ph.D.  
Manager of Quality Control  
35 South Street  
Hopkinton, Massachusetts 01748

Dear Dr. Kusmik:

Subject: Invitation to Enforcement Conference

An Enforcement Conference regarding the findings of the NRC Office of Investigations and the inspection conducted at Creative Biomolecules, Inc., facilities on November 10-11, 1992, will be conducted at the NRC Region I Office, King of Prussia, Pennsylvania, on June 7, 1994, at 10:00 a.m. Since our investigation and inspection activities included examination of your involvement relative to the investigation and inspection findings and you may be subject to enforcement action by the NRC, you are invited to attend the Enforcement Conference. (Directions to the Region I office are enclosed.) Your participation in the conference was discussed with you by Dr. Ronald R. Bellamy of this office on May 19, 1994.

The OI investigation concluded that (1) the Radiation Safety Officer (RSO) intentionally and deliberately directed an employee to falsify NRC required wipe test records; (2) the RSO made false or misleading statements to an NRC inspector; and (3) the RSO intentionally and deliberately provided false or misleading information to the NRC in a letter, dated September 21, 1992, in response to a Notice of Violation. You were designated as the RSO during the time of these activities.

The purposes of this conference are to: provide you the opportunity to discuss the OI findings, and provide your explanation with any mitigating or extenuating circumstances that will help us determine appropriate enforcement action. In addition, it will provide the licensee an opportunity to discuss the apparent violations, their cause(s) and safety significance; to point out any errors in our inspection report; and to present completed and proposed corrective actions. The proceedings of the meeting will be recorded. A copy of the NRC inspection report and OI synopsis were sent to you as distribution in a May 26, 1994 letter to Charles Cohen, Chairman of Creative Biomolecules, however, we are attaching additional copies to this letter.

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Appropriate enforcement action for the apparent violations will be considered by the NRC following the conference and you will be informed of that action by letter. A copy of the NRC Enforcement Policy which is described in Appendix C of 10 CFR Part 2, is enclosed for your information.

Should you have any questions or if you desire to have a separate enforcement conference, you should contact Dr. Ronald Bellamy, Nuclear Materials Safety Branch Chief at NRC, Region I, Telephone No. 610-337-5200.

In accordance with Section 2.790, of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the Public Document Room.

No reply to this letter is required. Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed by

Charles W. Hehl, Director  
Division of Radiation Safety  
and Safeguards

Enclosures:

1. Directions to the Region I Office
2. NRC Region I Inspection Report No. 030-19953/92-002
3. OI Synopsis
4. 10 CFR Part 2

cc:

Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Massachusetts  
Dr. Charles Cohen, Chairman of the Board  
and Chief Scientific Officer (Creative Biomolecules, Inc.)  
Hugh Scott, Esquire

bcc:

Region I Docket Room (w/concurrences)

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J. E. Glenn, NMSS

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M. Shanbaky, RI

S. Arredondo, RI

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