

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 23, 2005

Docket No. 03035426 Control No. 137429 License No. 06-30583-01

Louis Matis, M.D. President and Chief Executive Officer Cellular Genomics, Inc. C/o CGI Pharmaceuticals, Inc. 36 East Industrial Road Branford, CT 06405

SUBJECT: CELLULAR GENOMICS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 137429

Dear Dr. Matis:

This is in reference to your letter dated July 27, 2005, requesting to amend Nuclear Regulatory Commission License No. 06-30583-01 and to the telephone discussion between Bari Gabbitas of your organization and myself on August 23, 2005. In order to continue our review, we need the following additional information:

- 1. In your letter, you indicate that the name of the company has been changed to CGI Pharmaceuticals, Inc. During the telephone discussion, Ms. Gabbitas stated that the change in the name of the company was not due to a change in ownership. Please describe the reason for the change in name and why it is not a change in ownership.
- 2. While reviewing the license with Ms. Gabbitas, it was noted that one of the named researchers was no longer in the employ of the licensee, i.e., Changqing Wang, Ph.D. Please review your program to determine if there are to be any additional deletions or if you want to request that additional authorized users be placed on the license. Please provide the training and experience with radioisotopes for any additional authorized users.
- 3. In your letter, you make a request for a relaxation of your survey frequency for contamination from weekly surveys to monthly surveys. Please review the model procedure for surveys found in NUREG-1556, Volume 7, Appendix Q for guidance. The model procedure is based on the amount of licensed material used and can be adapted to the changing circumstances of the licensee's program. Please indicate whether you have adopted the model procedure or submit a procedure of your own.

Current NRC regulations and guidance are included on the NRC's website at <u>www.nrc.gov;</u> select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material;** then **toolkit index page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays). L. Matis Cellular Genomics, Inc.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 137429. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5075.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Steven Courtemanche

Steven Courtemanche Health Physicist Commercial and R&D Branch Division of Nuclear Materials Safety

cc: Bari Gabbitas, Radiation Safety Officer L. Matis Cellular Genomics, Inc.

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SISP Review Complete: (SRC) After declaring this document "An Official Agency Record" it <u>will</u> be released to the Public.

OFFICE	DNMS/RI	Ν	DNMS/RI	DNMS/RI		
NAME	SCourtemanche/src					
DATE	08/23/2005					

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