



CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health
Bureau of Environmental Health
Radiation Control Program

Schrafft Center, Suite 1M2A
529 Main Street, Charlestown, MA 02129
Phone: 617-242-3035 Fax: 617-242-3457
www.mass.gov/dph/rcp

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

April 20, 2018

Hilary King
Microbiology Analyst IV
Radiation Safety Officer
Avista Pharma Solutions
104 Gold Street
Agawam, Massachusetts 01001

RE: Amendment Number: 07
License Number: 48-0469
Docket Number: 21-2930

Dear Mr. King,

Enclosed is the above referenced license amended as requested in your letter dated September 26, 2017.

Please review the enclosed document carefully. If there are any errors or questions, please do not hesitate to contact this office at the number above.

Sincerely,

For

John M. Priest, Jr., Director
Radiation Control Program

JMP/jg
Enclosure: (1)



THE COMMONWEALTH OF MASSACHUSETTS
 DEPARTMENT OF PUBLIC HEALTH
 RADIATION CONTROL PROGRAM
 MATERIALS LICENSE

Pursuant to Massachusetts General Laws Chapter 111, Sections 3, 5M, 5N, 5O and 5P and Massachusetts Regulations for the Control of Radiation, Section 120.100, Licensing of Radioactive Material, and in reliance on statements and representation heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations 105 CMR 120.000. This license shall be deemed to contain the conditions specified in 105 CMR 120.000 and is subjected to all applicable rules, regulations of the Department of Public Health, Commonwealth of Massachusetts, now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Avista Pharma Solutions</p> <p>2. 104 Gold Street Agawam, Massachusetts 01001</p>	<p>3. License Number: 48-0469 is amended in its entirety, in accordance with the letter dated September 26, 2017, to read as follows:</p> <p style="padding-left: 40px;">Amendment No: <u>07</u></p> <hr/> <p>4. Expiration Date: June 30, 2019</p> <hr/> <p>5. Docket No: 10-4499</p>
-----------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

6. Radioactive Material	7. Chemical/Physical Form	8. Maximum Possession Limit
A. Hydrogen-3	A. Any	A. 100 millicuries
B. Carbon-14	B. Any	B. 90 millicuries
C. Copper-64	C. Any	C. 20 millicuries
D. Iodine-131	D. Bound (non-volatile)	D. 20 millicuries
E. Phosphorus-32	E. Any	E. 10 millicuries
F. Phosphorus-33	F. Any	F. 100 millicuries
G. Sulfur-35	G. Any	G. 100 millicuries

9. Authorized use:

A. through G. For purpose of sterility and endotoxin testing of drug products.

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM	LICENSE NUMBER: 48-0469
MATERIALS LICENSE SUPPLEMENTARY SHEET	DOCKET NUMBER: 10-4499
	AMENDMENT NUMBER: <u>07</u>

CONDITIONS


10. Radioactive materials shall only be used or stored at the licensee's facilities located at 104 Gold Street, Agawam, Massachusetts.
11. This license is subject to an annual fee as determined by the Executive Office for Administration and Finance.
12. A. Licensed material shall be used by, or under the supervision of, Liza Chenette or Hilary King.
B. The Radiation Safety Officer for this license is Hilary King.
13. Licensed material shall not be used in or on human beings.
14. The licensee shall not use radioactive material in field applications where activity is released except as provided otherwise by specific conditions of this license.
15. The licensee is authorized to hold radioactive material with physical half-lives of less than or equal to 90 days for decay-in-storage before disposal in ordinary trash as described in application dated February 11, 2014 provided:
 - A. Before disposal as ordinary trash, the radioactive waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each disposal permitted under this license condition shall be retained for three years. The record shall include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual(s) who performed the disposal.
16. The licensee shall only transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of 49 CFR Parts 170 through 189, 10 CFR Part 71, and 105 CMR 120.770 "Transportation of Radioactive Material."

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 48-0469
	DOCKET NUMBER: 10-4499
	AMENDMENT NUMBER: <u>07</u>

17. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including any enclosures, listed below. The Massachusetts Regulations for the Control of Radiation (105 CMR 120.000) shall govern, unless statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Renewal Application dated February 11, 2014
 - B. Letter dated May 12, 2014
 - C. Letter dated May 16, 2014
 - D. Electronic mail message dated June 3, 2014
 - E. Letter dated July 15, 2014
 - F. Letter dated October 30, 2014
 - G. Letter dated December 2, 2014
 - H. Letter dated September 26, 2017 with attachments
 - I. Electronic letter dated January 18, 2018 with attachments
 - J. Electronic letter dated January 19, 2018

FOR THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

Date 4/24/2018

By 
For John M. Priest, Jr., Director

