

FEDERAL COURT

BETWEEN:


FEDERAL COURT
COUR FÉDÉRALE
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JAN 09 2015

NEIL ALLARD
TANYA BEEMISH
DAVID HEBERT
SHAWN DAVEY

SERVICE OF A TRUE COPY
HEREOF ADMITTED

JAN 09 2015

WILLIAM F. PENTNEY
PLAINTIFFS for
A.G.C.

Date: _____
Registrar: 
Clerk: _____

AND:

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

DEFENDANTS

AFFIDAVIT OF ERIC J. M. NASH

I, Eric John MacArthur Nash, Chief Operating Officer of Island Harvest Inc., of the City of Duncan, in the Province of British Columbia, MAKE OATH AND SAY AS FOLLOWS, THAT:

1. I make this affidavit of my own personal knowledge, information and belief. Where matters are stated to be on information and belief, I so indicate and believe them to be true.
2. I have been asked to provide information based on my experience with Health Canada's regulatory framework for the medicinal use, production, distribution and sale of cannabis under the *Marihuana Medical Access Regulations (MMAR)* and the *Marihuana for Medical Purposes Regulations (MMPR)*.
3. I have been involved in the Health Canada medical cannabis access program since August 31, 2001.

4. I have worked as co-owner of two Canadian medical cannabis-based businesses, Island Harvest Inc. and PhytoCan Pharmaceuticals Inc.
5. I have been cultivating, distributing and selling cannabis for medical purposes as a designated licensed producer since 2002 under the company name of Island Harvest. The regulatory framework for the production and distribution was facilitated under Health Canada's *Marihuana Medical Access Regulations (MMAR)*.
6. Our company and our medical marihuana have received organic certification for five consecutive years from the Pacific Agricultural Certification Society (PACS) and the Certified Organic Associations of British Columbia (COABC). The organic regulations are administered by the British Columbia Ministry of Agriculture, Food and Fisheries, and our cannabis crop has been inspected.
7. Our company has produced successive crops of cannabis over a period of more than ten years. The crops consist of several strains (or hybridized plant varieties) which are available in commercial seed catalogues. These include both indica and sativa dominant cannabis plant species.
8. In 2004 I was invited to participate in Ottawa as advisor to Health Canada's Multi-Stakeholder Consultation session on the *Marihuana Medical Access Regulations (MMAR)* to provide input on policy development and future regulatory framework of the federal medical cannabis access program.
9. On February 18, 2004 I attended the Health Canada stakeholder meeting in Ottawa representing a group of over 100 *MMAR* licencees and I presented a number of recommendations to Health Canada on amendments to the *MMAR*.
10. In 2005 I was contacted by the Research and Analysis Section of the United Nations Office on Drugs and Crime in Vienna and asked to provide input and data on cannabis crop yields for their Global Cannabis Study.

11. In 2005 I was appointed to the National Cannabis Steering Committee by the Canadian AIDS Society. The project culminated in 2006 with significant findings on the use of medical cannabis in Canada.

12. In 2007 I was contacted by Brian Thiessen, Staff Sergeant and Program Manager at the Pacific Region Canadian Police Research Centre and Sgt. Rick Parent Ph.D., Manager at the Research and Academic Development, Justice Institute of British Columbia Police Academy. On behalf of PhytoCan Pharmaceuticals and Island Harvest, we agreed to a collaborative venture with the Canadian Police Research Centre and Titan Analysis Ltd. to conduct scientific research on cannabis plants pending Health Canada's approval.

13. In 2008, I attended the United Nations General Assembly Special Session on international drug policy to provide input on regulatory framework models for medical cannabis distribution protocol.

14. In 2010 and 2011, I was invited by Health Canada's Director General, Cathy Sabiston, and Health Canada's Office of Policy and Strategic Planning, to meet and provide input on the future of the Canadian federal medical cannabis access program from the perspective of a long-time licensed producer and distributor.

15. On July 7, 2010, I attended a meeting in Vancouver with Director General Cathy Sabiston and Health Canada officials to discuss matters pertaining to the regulatory transition from the *MMAR* to the current *Marihuana for Medical Purposes Regulations*.

16. On September 7, 2011, I attended a closed meeting in Vancouver with Director General Cathy Sabiston and Health Canada officials to discuss the Government of Canada's proposed improvements to Health Canada's Marihuana Medical Access Program and to provide input on the policy reform.

17. On February 15, 2012, I attended a meeting in Victoria B.C. with Health Canada officials. The meeting in Victoria was for those who had expressed interest in becoming licensed commercial producers under the new *Marihuana Medical Access Program* (MMAP). Health Canada was seeking input on what the regulatory requirements could

be in regards to commercial production, specifically for technical input advice on quality, security and record keeping practices for growing and manufacturing marihuana for medical purposes. This meeting was specifically intended for individuals with technical background knowledge in the above mentioned areas.

18. In 2012, 2013 and 2014, I have worked as Chief Operating Officer of Island Harvest Inc., a British Columbia based medical cannabis company. I have prepared the operational infrastructure, facility and government application for commercial cannabis production under Health Canada's new *Marihuana for Medical Purposes Regulations (MMPR)* and have ensured compliance with all applicable bylaws and regulations.

19. Over the past several years, Island Harvest, as a designated producer and supplier of medical cannabis under the *Marihuana Medical Access Regulations (MMAR)*, has had continued political support from every level of local government, including federal, provincial, city and regional authorities.

(a.) Government support letters are produced and marked as Exhibit "A" to this my Affidavit.

20. On July 8, 2013, as per the *MMPR* application process, I mailed Island Harvest's personnel security clearance documents to Health Canada via registered mail. The documents were received in Ottawa on July 11, 2013. Enclosed were the following documents:

- a. Security Clearance Application Forms (2)
- b. Security Clearance Fingerprint Third Party Consent to Release Personal Information Forms (2)
- c. RCMP/GRC Fingerprint Forms C-216C (2)
- d. Copies of valid provincial photo identification (2)

21. On August 15, 2013, Island Harvest Inc. signed a lease on an industrially zoned property located in Duncan, British Columbia for medical cannabis production and activities relating to medicinal marihuana. The concrete building has steel doors, no windows and the facility was previously used for commercial food production.

22. On August 21, 2013, Island Harvest Inc. signed a letter of engagement and retained Margaret Daskis as Island Harvest's Quality Assurance and Quality Control person.

23. Margaret Daskis is one of Canada's most highly-experienced and well-respected national award-winning quality control experts with over 30 years' experience and technical expertise in the field. Margaret has developed numerous Standard Operating Procedures, Policy Manuals, conducted recalls and performed scientific operating and testing procedures throughout Canada. Ms. Daskis held the top Quality Assurance and Quality Control position at Nalley's Canada Ltd. for over a decade. As "*Director of Quality Assurance and Research & Development*", no other position within Nalley's Canada usurped her Quality Assurance authority.

24. Margaret Daskis is the 2012 recipient of the Canadian Institute of Food Science and Technology's (CIFST) National Food Safety and Quality Award for outstanding contribution to Canadian industry throughout her extensive career. The CIFST is the national association for food industry professionals and its membership of more than 1200 is comprised of scientists and technologists in industry, government and academia.

25. On August 27, 2013, our company Island Harvest Inc. applied to Health Canada under the *Marihuana for Medical Purposes Regulations (MMPR)* to obtain Licensed Producer (LP) status at Level 5 of the *Directive on Physical Security Requirements for Controlled Substances* for the commercial production, distribution and sales of medical cannabis.

(b.) August 27, 2013 MMPR application cover letter from Island Harvest to Health Canada is produced and marked as Exhibit "B" to this my Affidavit.

26. Island Harvest's complete application package was mailed on August 27, 2013 and received in Ottawa by Health Canada on August 29, 2013.

27. On Tuesday, September 3, 2013 I received a confirmation email from the *Office of Controlled Substances (OCS)* at Health Canada's *Licenses and Permits Division*,

stating "Your application package has been received and it will be reviewed in a timely manner." Our file number was confirmed and noted as 10-MM0102.

(c.) September 3, 2013 Health Canada *MMPR* application confirmation email to Island Harvest is produced and marked as Exhibit "C" to this my Affidavit.

28. On September 9, 2013, Island Harvest received a two-page "Screening Letter" via email from Health Canada with a series of questions pertaining to Section 8 of the application form (Proposed Site and Physical Security), Section 10 of the application form (Quality Assurance Pre-Licensing Report) and Section 11 of the application form (Record Keeping).

29. On September 20, 2013 and September 23, 2013, I sent the requested information to Health Canada's Licenses and Permits Division.

30. On October 10, 2013 I requested a "Ready to Build" letter from Health Canada to obtain governmental facility assurance for Island Harvest's financial project funding. Health Canada issues "Ready to Build" letters to *MMPR* applicants upon request after completion of the paper review process.

31. On October 29, 2013 Island Harvest received a seven-page "Review Letter" via email from Health Canada with a series of questions pertaining to Section 8 of the application form (Proposed Site and Physical Security), Section 10 of the application form (Quality Assurance Pre-Licensing Report) and Section 11 of the application form (Record Keeping).

32. On November 29, 2013, as per Health Canada's request, I sent the additional requested response information to the *Licenses and Permits Division*.

33. On December 12, 2013, I received a four-page request letter from Health Canada requesting additional file information on Record Keeping and source of plant starting materials.

34. On December 12, 2013, I sent the requested information to Health Canada's *Licenses and Permits Division* regarding record keeping, source of plant starting materials and I again requested a "Ready to Build" letter.

35. On December 23, 2013, Island Harvest received a four-page "Request for more information letter" via email from Health Canada with a series of questions pertaining to Section 8 of the application form (Proposed Site and Physical Security), Section 10 of the application form (Quality Assurance Pre-Licensing Report) and Section 11 of the application form (Record Keeping).

36. On January 23 and 24, 2014, as per Health Canada's request, I sent the additional requested response information to the *Licenses and Permits Division*.

37. On January 24, 2014 I sent a letter via email and registered mail via Canada Post requesting a "Ready to Build" letter from Health Canada for obtaining Island Harvest's financing. Health Canada received Island Harvest's "Ready to Build" request letter on January 31, 2014.

(d.) Island Harvest's January 24, 2014 request for a "Ready to Build" letter to Health Canada is produced and marked as Exhibit "D" to this my Affidavit.

38. On January 24, 2014, I received an email from Health Canada's *Licenses and Permits Division* at the *Office of Controlled Substances* outlining the five (5) steps in processing an application to become a Licensed Producer under Health Canada's *Marihuana for Medical Purposes Regulations (MMPR)*.

39. The five steps in processing an application for Licenced Producer status under the *MMPR* are: Screening, Reviewing, Ready to Build, Pre-Licence Inspection and Issuance of Licence.

(e.) January 24, 2014 "MMPR Application Processing Steps" email is produced and marked as Exhibit "E" to this my Affidavit.

40. On February 24, 2014, Island Harvest received a "Ready to Build" approval letter from Health Canada (OF15-59-1484-34) deeming that our application is satisfactory and

meets the requirements of the *MMPR*. The *Ready to Build* letter is dated February 19, 2014.

(f.) Health Canada "*Ready to Build*" letter, dated February 19, 2014, is produced and marked as Exhibit "F" to this my Affidavit.

41. The "*Ready to Build*" letter confirmed our Security Level 5 status, as specified in Health Canada's *Directive on Physical Security Requirements for Controlled Substances*.

42. The "*Ready to Build*" letter from Health Canada, dated February 19, 2014 states "*your proposal meets the requirements of the quality assurance pre-licensing report and record keeping requirements of the MMPR.*" Island Harvest's license is then subject to final physical security inspection and licencing approval.

43. The "*Ready to Build*" letter from Health Canada advises our company as follows: "*Please inform us when you have completed your security installation and the electronic security is functional. We will arrange for the pre-licence inspection. The inspection will confirm compliance with all requirements of the MMPR, including the security of the cultivation area and the security of the storage area.*"

44. The "*Ready to Build*" letter concludes with "*Once a pre-licence inspection has been conducted to verify compliance with the requirements under the MMPR and the key personnel identified in your application have received the security clearance required under the MMPR, a producer's licence will be issued.*"

45. On February 24, 2014, Island Harvest retained Camacc Systems for design and installation of the security system as per the *MMPR*, our application submission, and Health Canada's *Directive on Physical Security Requirements for Controlled Substances*. Camacc is one of Canada's leading award-winning national security firms. A few of their clients include organizations such as Chevron, Petrocan, Shell Oil, Imperial Oil, U.S. Department of Justice and Homeland Security, as well as many Canadian government offices, corporations, casinos and institutions including the R.C.M.P.

46. In respect to Island Harvest's Record-Keeping methods, our system was approved for the *MMPR* in February 2014 by Health Canada's comprehensive LP review process.

47. In March 2014, after Island Harvest received Health Canada's Security Level 5 "*Ready to Build*" letter, we commenced work in our leased facility to prepare for the pre-licence inspection. This work included installation of the security systems: access control system, video monitoring system and intrusion detection and monitoring system.

48. On May 21, 2014, I sent Health Canada a written request for confirmation of Island Harvest's personnel security clearances approvals.

(g.) May 21, 2014 Personnel Security Confirmation Request letter to Health Canada is produced and marked as Exhibit "G" to this my Affidavit.

49. On May 28, 2014, I sent an email to Health Canada informing the *Licences and Permits Division* that Island Harvest is ready for the *MMPR* pre-licence inspection.

50. On June 3 and June 5, 2014, I sent Health Canada emails requesting scheduled date(s) of our pre-licence inspection.

51. On June 5, 2014, I received an email from Health Canada confirming that Island Harvest's personnel security clearances had been approved.

52. The June 5, 2014 email from Health Canada also stated that prior to our pre-licence inspection, there were a few validation questions: "*We have received the results of your security checks this week and we will be able to move forward with the final review of 10-MM0102. We have a few validation questions prior to scheduling an inspection. Please clarify the following information by the requested date.*"

53. The validation questions were pertaining to Section 10 of the application form (Quality Assurance Pre-Licensing Report) and Section 11 of the application form (Record Keeping).

54. The June 5, 2014 email from Health Canada also stated, "*We would like you to note that if the inspection is successful and you are granted an MMPR licence, this will be*

contingent on an upgrade to a minimum security level 7 vault within the next 12 months."

55. This was the first time I was notified by Health Canada about their condition for a change in our physical security level status. The security levels are based on the amount of dried product stored at the facility. As stated in our *MMPR* application, Island Harvest would be storing a maximum of 5 kilograms of dried cannabis bud in the facility.

56. Health Canada places the value of dried cannabis bud at \$10,000 per kilogram. The Island Harvest facility would store a maximum of \$50,000 of dried product. This amount of dried cannabis and the corresponding value, places Island Harvest at a Level 5, as per Health Canada's *Directive on Physical Security Requirements for Controlled Substances*, which is the document for *MMPR* reference.

57. On June 20, 23 and 24, 2014, I responded to Health Canada, answering all the "validation questions" prior to the pre-licence inspection. In my email letters to Health Canada, I again requested the confirmation of our scheduled pre-licence inspection date.

58. On June 3 and June 25, 2014, I received two additional emails from Health Canada with further validation questions. The emails also stated, "*We would like you to note that if the inspection is successful and you are granted an MMPR licence, this will be contingent on an upgrade to a minimum security level 7 vault within the next 12 months.*"

59. On June 29, 2014, I responded to Health Canada, answering all the validation questions prior to the pre-licence inspection. I asked again about possible dates for our pre-licence inspection.

60. On July 2, 2014, I received an email from Health Canada requesting additional information on the Quality Assurance component of our application. Health Canada requested information about our quality assurance person "*to demonstrate that they have the proper training, knowledge and technical expertise to conduct their required duties*".

61. The July 2, 2014 email from Health Canada stated: "*Please provide us the information requested in this letter by close of business on July 23, 2014. If you do not respond by this date the Minister must refuse to issue a producer's license pursuant to section 26 of the MMPR and your file will be closed.*"

62. The July 2, 2014 email from Health Canada also stated: "*We would like you to note that if the inspection is successful and you are granted an MMPR licence, this will be contingent on an upgrade to a minimum security level 7 vault within the next 12 months.*"

63. On July 22, 2014, I responded to Health Canada's request, providing all the required information pertaining to our quality assurance person's qualifications, including lists of quality control activities and related corresponding schedules.

64. On July 14, 2014, I phoned and spoke with Jacinthe David at Health Canada and asked Ms. David for the date of our scheduled pre-licensing inspection. Jacinthe David told me that "*We've been avoiding your inspection because we're upgrading everyone to a level 7 security.*" She also added that Health Canada will not inspect a Level 5 facility.

65. After a one year application file processing time, Monday, July 14, 2014 was the first time our company was advised that the *Licences and Permits Division* will not inspect a level 5 facility, which Health Canada had previously approved in a signed letter to us.

66. Island Harvest was issued a signed Level 5 "*Ready to Build*" approval letter by Health Canada and our company built our facility to the exacting standards of the Level 5 security directive at significant operational expense under a long-term lease.

67. Between July 2 and July 18, 2014, I wrote to several Health Canada senior departmental officials requesting confirmation of our pre-licencing inspection date.

68. On July 15, 2014, I received an email from Health Canada in regards to my correspondence with senior Health Canada departmental officials.

69. The July 15, 2014 email from Health Canada stated: *"It has to come to our attention that you have been corresponding with other Health Canada officials regarding your application to become a licensed producer under the Marihuana for Medical Purposes Regulations (MMPR). Please note that the MMPR inbox should be used for all communications regarding your application... as of July 1, 2014 a minimum security level 7 is required for an application to be considered. Additional information will be provided to you on this in the coming weeks."*

70. The July 15, 2014 email stated that Health Canada had imposed a mandatory minimum Security Level 7 for the MMPR application process. This was the first time I heard about this new regulatory change being a mandatory minimum. I was unable to confirm any additional details about this policy amendment and was not advised further from Health Canada with any information on this new policy change or directive. It seemed that Health Canada had eliminated all security levels below level 7 for the MMPR program without any notice.

(h.) July 15, 2014 email from Health Canada eliminating Security Level 5 and 6 is produced and marked as Exhibit "H" to this my Affidavit.

71. On July 18, 2014, I received an email from Health Canada's Office of Controlled Substances. The July 18 Health Canada email stated the following: *"This letter is to inform you that applicants under the MMPR must now meet, at a minimum, a level 7 under the Physical Security Directive for their security requirements. We are contacting you today because your application currently does not meet this requirement. In order for the processing of your application to continue, you must submit a revised physical security proposal showing how you will meet, at a minimum a level 7. Information on the requirements for a level 7 and up can be found on the Health Canada website"*.

(i.) July 18, 2014 email from Health Canada stating mandatory minimum Security Level 7 is produced and marked as Exhibit "I" to this my Affidavit.

72. There is nothing stated in the *Application to Become a Licensed Producer Under the Marihuana for Medical Purposes Regulations (MMPR)* about a minimum security level 7 security requirement.

73. There is nothing stated in Health Canada's *Guidance Document on Building and Production Security Requirements for Marihuana for Medical Purposes* about a minimum Level 7 security requirement for the *MMPR*.

74. There is nothing stated in Health Canada's *Directive On Physical Security Requirements For Controlled Substances* about a minimum Level 7 security requirement.

75. I have been unable to find any document pertaining to the *MMPR* application process stating that Health Canada has changed the security levels for assigned monetary values of controlled substances, specifically cannabis in regards to the licencing requirements.

76. As a Licenced Producer (LP) applicant, Island Harvest has been approved in writing by Health Canada for Level 5 security at our site for the *Marihuana for Medical Purposes Regulations (MMPR)*.

77. I have received no additional information from Health Canada regarding a Level 7 security amendment to Health Canada's *Directive on Physical Security Requirements for Controlled Substances*, or an amendment to any Health Canada policy change on the elimination of Security Level 5 and 6 for the security directive pertaining to controlled substances.

78. On July 18, 2014, I wrote an email to Deputy Health Minister George Da Pont at Health Canada regarding the apparent change in the Security Directive for the *MMPR*.

79. I was not aware of Health Canada's security directive change until after building our facility to the assigned Level 5 standards, as stated in Health Canada's "*Ready to Build*" letter to Island Harvest from February 2014.

(j.) July 18, 2014 email to George Da Pont Deputy Minister of Health from Island Harvest, is produced and marked as Exhibit "J" to this my Affidavit.

80. On July 15, 2014, I arranged a meeting with our Member of Parliament, Jean Crowder MP, to assist in facilitating a resolution with Health Canada pertaining to our *MMPR* Licenced Producer application. On July 22, 2014, I met with Jean Crowder MP.

81. On August 12, 2014, Island Harvest Inc. joined the Canadian Medical Cannabis Association (CMCIA). The Canadian Medical Cannabis Industry Association is Canada's leading member-driven association for Licensed Producers (LPs) of medical cannabis.

82. On October 9, 2014, I sent an email with Island Harvest's security upgrade proposal regarding the storage component of the regulations. The document I sent was titled "*Physical Security Upgrade for Product Storage to Level 7 as per recent MMPR policy change*". It included floor plan schematics, photos and technical specifications to comply with Health Canada's new mandatory minimum Level 7 change to the security directive.

83. On October 30, November 25 and December 2, 2014 I sent emails to Health Canada requesting updated information pertaining to our *MMPR* file.

84. On November 7, 2014 I wrote an email to Deputy Health Minister George Da Pont at Health Canada communicating a summary of our company's experience with Health Canada's *Office of Controlled Substances* and the *Licences and Permits Division* in regards to the licensing process under the *Marihuana for Medical Purposes Regulations*.

85. My letter to Deputy Health Minister Da Pont begins with the following: "*I am writing to you with very serious concerns about irregularities, deficiencies and contradictions regarding the regulatory process and policy framework with application file processing at Health Canada's Office of Controlled Substances under the Marihuana for Medical Purposes Regulations (MMPR).*"

(k.) November 7, 2014 email to George Da Pont Deputy Minister of Health from Island Harvest, is produced and marked as Exhibit "K" to this my Affidavit.

86. On November 8, 2014 I received an email response from Deputy Health Minister George Da Pont regarding my previous email. Deputy Minister Da Pont responded by writing, "*This is to acknowledge receipt of your e-mail. I will look into the matter.*"

(l.) November 8, 2014 email from George Da Pont Deputy Minister of Health to Island Harvest, is produced and marked as Exhibit "L" to this my Affidavit.

87. On November 20, 2014, I spoke on the phone with Brigitte Lucke, Health Canada's Director General of the *Office of Controlled Substances*. On November 20, Brigitte Lucke assured me that I would receive a response from Health Canada within a few days.

88. On December 9, 2014, I sent an email to Director General Brigitte Lucke advising her that I had not received anything from Health Canada pertaining to Island Harvest's file.

89. On December 9, 2014, I received an email from Jean Crowder MP's office in regards to our file with Health Canada. It stated: "*The minister's office has informed me that they have no new information to provide and cannot provide any information until you hear directly from the department. Coming from the minister's office, this answer is simply not acceptable. I have responded and asked for some ministerial accountability on behalf of the department in question.*"

(m.) December 9, 2014 email from Constituency Assistant Alistair MacGregor at Jean Crowder MP's office to Eric Nash of Island Harvest, is produced and marked as Exhibit "M" to this my Affidavit.

90. On December 10, 2014, Brigitte Lucke from Health Canada emailed me and said that she would be responding to me in two days. Three weeks later I received a letter.

91. On December 29, 2014, Island Harvest received a seven-page letter via email from Health Canada with a further lengthy series of questions pertaining to the following:

- Section 5 of the application Form: Activities to be Specified on the Licence
- Section 6 of the application form: Proposed Site Information

- Section 8 of the application form: Proposed Site and Physical Security
- Section 10 of the application form: Quality Assurance Pre-Licensing Report
- Section 11 of the application form: Record Keeping

92. In the December 29, 2014 letter from Health Canada, in addition to Health Canada's request for information pertaining to various sections of the application form, I was also requested to provide a business plan as follows: *"Please provide us with a copy of your business plan, including projected sales and production on dried marijuana for 12 months forecast. This forecast should include, but not be limited to: production, inventory, sales, shipments and size of shipments, the crops underway, and expected yields. Please indicate how you intend to produce the amount based on the available growing areas at your premises. We also require detailed information on how you intend to acquire clients and your capacity to sell the amount that you have projected on a monthly basis. These forecasts should represent your best estimate of the amount of dried that you will produce incorporating such factors as: expected number of registered clients and others."*

93. There is no requirement mentioned in the *Application to Become a Licensed Producer under the Marijuana for Medical Purposes Regulations (MMPR)*, or specified in any other government document I have seen, in regards to providing a business plan to Health Canada as part of the application process to become a Licenced Producer.

94. Since August 2013, our company Island Harvest Inc., has been thoroughly and rigorously screened and reviewed by Health Canada. In February 2014, we were notified by Health Canada that Island Harvest's *"proposal meets the requirements of the quality assurance pre-licensing report and record keeping requirements of the MMPR."*

95. On June 5, 2014 we received notice from Health Canada that our company personnel security clearances were approved. Our site has been approved at Level 5 security for medical cannabis production under the *MMPR*. The Island Harvest facility has been ready for the pre-licence inspection since June 2014. We have been waiting for Health Canada to inspect our Island Harvest site for over six months.

96. As a small Canadian company business entering the *MMPR* program as a Licenced Producer applicant, I have found the application process onerous, problematic and illusory, with the regulatory requirements constantly changing without notice and very poor communication from Health Canada with us as an applicant. From my experience, it seems as though Health Canada is deliberately attempting to stall and obfuscate the *MMPR* application process creating very significant barriers to entry.

97. I have been contacted by many other *MMPR* applicants who are experiencing the exact same problem with Health Canada's *Office of Controlled Substances* and the *Licences and Permits Division*. The regulatory "goal posts" are constantly moving, with little or no communication with *MMPR* applicants or the public in regards to policy directive amendments, regulation changes or guideline updates.

98. I have read and reviewed the affidavit of Todd Cain from Health Canada dated February 7, 2014 that was filed by the Defendant Canada in opposition to the Plaintiff's injunction application that can be found posted at www.johnconroy.com under the link to the *MMAR* Constitutional Challenge and specifically under C. The Motion for the interim or Interlocutory Injunction pending trial. 2. The Government of Canada evidence opposing the motion; c. The affidavit of Todd Cain from Health Canada of February 7, 2014 and exhibits "A" through "E";

99. I have found through my involvement as a *MMPR* Licensed Producer applicant, there are several discrepancies between my experience with the *MMPR* application process and what has been described in Todd Cain's affidavit.

100. Todd Cain's affidavit (paragraph 19) refers to "*industry engagement*" and "*streamlined processes for processing applications*", which doesn't reflect our company's experience with the prolonged and ambiguous *MMPR* application process.

101. Todd Cain writes (paragraph 22), "*A case management approach was also adopted, which involves appointment of case managers to work with applicants to complete the review process and to enhance timely processing of applications.*"

102. On several occasions I have spoken with Health Canada's *Office of Controlled Substances* and the *Licences and Permits Division* in regards to our file. Health Canada has informed me both verbally and in writing that no case managers are assigned to individual files to assist applicants by answering questions or providing timely file processing.

103. Correspondence from Health Canada regarding questions from *MMPR* applicants are answered anonymously, so that it is impossible for the applicant to refer specific responses to the individuals responsible for their file at Health Canada.

104. On January 5, 2015, I received an email from Health Canada's Office of Controlled Drugs stating "*There are no case managers assigned to individual files.*"

105. In regards to the "*Ready to Build*" letters issued by Health Canada, Todd Cain's statement (paragraph 23.a.) states "*These letters advise applicants that if they complete their site build as described in their application, if the site is verified by a pre-licence inspection, and if security clearances are granted, the applicant's licence can be issued.*"


106. I have experienced through Island Harvest's corporate application with the *MMPR* application process, if Health Canada issues a "*Ready to Build*" letter, and the applicant builds their site as described in their application, and all personnel security clearances are granted, Health Canada will not conduct a pre-licence inspection.

107. Island Harvest was issued a *Ready to Build* letter, we built our site as described in our application, our personnel security clearances were granted, and our site has still not been inspected after several months of waiting.

108. My November 7, 2014 email letter to Deputy Health Minister George Da Pont describes my experience with Health Canada's *MMPR* Licenced Producer application process: "Health Canada is clearly moving the regulatory goalposts of the *MMPR* to obfuscate the application process to limit businesses entering the market, which has nothing to do with their supposed mandate of ensuring public health, safety or security... I am astounded and appalled at the disingenuous behaviour of Health Canada with the unimaginably slow file processing times of over one year, with Island Harvest's application now approaching 18 months, with no foreseeable end in sight."

109. I have discovered that Health Canada has stalled our application, delayed communications, changed regulations without notice to industry applicants, failed to respond in a timely manner and generally ensured that the *MMPR* application process is as laborious, misleading and as difficult as possible for our company as a Licensed Producer applicant. I see no indication that these actions by Health Canada will change in the future based on my past experience and background as a *MMPR* applicant.

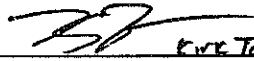
110. I swear this Affidavit as my evidence on behalf of the Plaintiffs in this action with respect to my experiences in relation to the *MMPR* application process.

SWORN BEFORE ME at the City)
of Duncan, in the Province of)
British Columbia, this 8th day of)
January, 2015)
)
)
)
A Commissioner for Taking Affidavits in)
and for the Province of British Columbia)


ERIC J. M. NASH

EXHIBIT "A"

This is Exhibit "A" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


Kirk Talbot, Barrister

A commissioner for taking affidavits
For British Columbia



CITY OF DUNCAN

October 19, 2011

Island Harvest
1000 Hutchinson Rd.
Cobble Hill, BC V0R 1L4

To Whom It May Concern:

RE: Letter of Support

On behalf of the City of Duncan, I am pleased to provide this letter of support for the proposed Island Harvest business expansion.

The City acknowledges that Island Harvest has an excellent track record. They have been in business in the Cowichan Valley since 2002 supplying high quality medical cannabis to patients requiring pain relief from various health conditions.

We are confident that Island Harvest's proposed business expansion will create safe long-term community economic growth and we are fully in support of their expansion efforts.

Sincerely,

Lynn Ketch
Director of Corporate Services



Jean Crowder, MP

Nanaimo-Cowichan



September 15, 2011

Island Harvest
1000 Hutchinson Road,
Cobble Hill, BC
V0R 1L4

**RE: Letter of Support for Island Harvest,
Regional Economic Development and Employment Opportunities**

Dear Ms. Little, Eric Nash and Island Harvest,

As the MP for Nanaimo-Cowichan I am pleased to offer my support for your proposed Island Harvest business expansion. I recognize that Island Harvest is a stable business in Cowichan producing a high quality product for people requiring relief from pain. Your new local business will create jobs, provide economic benefits and encourage similar businesses to grow and prosper in Cowichan and beyond. This expansion will also undoubtedly increase production and ensure the supply of a high quality product to people who rely on medical cannabis.

In closing, I support the proposed expansion and development of Island Harvest in Cowichan.

Sincerely,

Jean Crowder, MP
Nanaimo-Cowichan

Parliamentary Office

Room 650D, Centre Block
House of Commons
Ottawa, ON K1A 0A6

Tel: (613) 943-2180 Fax: (613) 993-5577

Email: jean@jeancrowder.ca

Community Office

101-126 Ingram Street
Duncan, BC V9L 1P1

Tel: (250) 746-4896 or 1-866-609-9998

Fax: (250) 746-2354

Website: www.jeancrowder.ca



Constituency Office:

524 - 1st Avenue, Box 269
Ladysmith, BC V9G 1A2
Telephone: 250 245-9375
Facsimile: 250 245-8164

Unit 112 - 50 Tenth Street
(Southgate Shopping Centre)
Nanaimo, BC V9R 6L1
Telephone: 250 716-5221
Facsimile: 250 716-5222

Legislative Office:

Parliament Buildings
Victoria, BC V8V 1X4
Telephone: 250 953-4739
Facsimile: 250 387-4680
e-mail: douglas.routley.mla@leg.bc.ca
website: www.dougroutley.ca



**Province of
British Columbia
Legislative Assembly**



Doug Routley, MLA
(Nanaimo-North Cowichan)

September 14, 2011

Island Harvest
1000 Hutchinson Road
Cobble Hill, B.C. V0R 1L4

RE: Letter of Support for Island Harvest

Dear Ms. Little and Mr. Nash,

Your company Island Harvest has been successfully operating in the Cowichan Valley for many years under Federal and Provincial licensing, providing high quality certified organic medical cannabis to people with conditions such as cancer, multiple sclerosis, HIV/AIDS, arthritis and chronic pain.

It is important to note that you are providing an important and recognized health product, which improves the quality of life for so many people requiring relief from pain and other serious medical conditions.

I would like to offer my support for Island Harvest as a licensed commercial producer and supplier of medical cannabis. This new area of agriculture creates jobs and provides significant economic benefits to the community. I look forward to your continued success.

Sincerely,

Doug Routley, MLA
Nanaimo – North Cowichan



CITY of DUNCAN

P.O. BOX 820

TELEPHONE: (250) 746-6126
FAX: (250) 746-6129

200 CRAIG STREET

DUNCAN, B.C.
V9L 3Y2

September 28, 2004

Island Harvest
693 Powell Street
Duncan, BC
V9L2V9

ATTN: Wendy Little and Eric Nash

Dear Ms. Little and Mr. Nash:

RE: Proposed Island Harvest Business Expansion

The Mayor and Council of the City of Duncan are most pleased to support the proposed business expansion of Island Harvest for medicinal cannabis production.

The positive long-term impact of this business expansion encourages strong support from our community.

Yours truly

CITY OF DUNCAN

Paul Douville
City Administrator

PD/lk

"CITY OF TOTEMS"



Province of
British Columbia
Legislative Assembly

Doug Routley, MLA
(Cowichan-Ladysmith)
Community Office:
273 Trunk Rd
Duncan, BC
V9L 2P3
Phone: (250) 746-8770



Doug Routley, MLA
(Cowichan-Ladysmith)

Island Harvest
693 Powell Street
Duncan, B.C. V9L 2V9

January 20, 2006

Dear Ms. Little and Mr. Nash,

Your company Island Harvest has been successfully operating in the Cowichan Valley for many years under federal and provincial licensing, providing high quality certified organic medical cannabis to people with conditions such as cancer, multiple sclerosis, HIV/AIDS, arthritis and chronic pain.

I understand that British Columbia's Ministry of Finance incorporates organizations known as compassion clubs, which supply thousands of BC residents with cannabis for medical purposes under physicians' recommendations. I also recognize that the clubs are unable to obtain a legally regulated consistent medical cannabis supply, which is a significant problem for these provincially licensed organizations.

The Health Officers Council of British Columbia recently released the 2005 "Public Health Approach To Drug Control in Canada", which places cannabis within a medical legally regulated framework of product management, distribution and sales.

It is important to note that you are providing an important and recognized health product, which improves the quality of life for so many people requiring relief from pain and other serious medical conditions.

I would like to offer my support for Island Harvest as a legally regulated supplier of medical cannabis to the licensed medical cannabis distribution centers, currently known as compassion clubs. This new area of agriculture creates jobs and provides significant economic benefits to the community. I look forward to your continued success.

Sincerely,

Doug Routley, MLA
Cowichan-Ladysmith



Jean
Crowder

MP for Nanaimo - Cowichan



September 20, 2004

Island Harvest
693 Powell Street
Duncan, B.C.
V9L 2V9

**RE: Letter of Support for Island Harvest
Regional Economic Development and Employment Opportunities**

Dear Ms. Little, Eric Nash and Island Harvest,

As the MP for Nanaimo-Cowichan I am pleased to offer my support for your proposed Island Harvest business expansion. I recognize that Island Harvest is a stable business in Cowichan producing a high quality product for people requiring relief from pain.

Your new local business will create jobs, provide economic benefits and encourage similar businesses to grow and prosper in Cowichan and beyond. This expansion will also undoubtedly increase production and ensure the supply of a high quality product to people who rely on medical cannabis.

In closing, I support the proposed expansion and development of Island Harvest in Cowichan.

Sincerely,

A handwritten signature in cursive script that reads "Jean Crowder".

Jean Crowder
MP Nanaimo-Cowichan



Province of British Columbia
Legislative Assembly

Graham P. Bruce, M.L.A.
Cowichan-Ladysmith

Constituency Office:
101 - 455 Alderlea Street
Duncan BC V9L 3V3
Telephone: 250 715-2900
Facsimile: 250 715-2909
Toll-Free: 1 866 215-7500
e-mail: graham.bruce.mla@leg.bc.ca

September 15, 2004

Wendy D. Little, B.Ed.hon.
Eric J.M. Nash, B.F.A.hon.
Island Harvest,
693 Powell Street,
Duncan, BC V9L 2V9

Dear Ms. Little and Mr. Nash,

The Cowichan Valley has generated many different types of businesses over the years and it is always gratifying when their success demands expansion and creates job opportunities for people in the community.

Your company Island Harvest is proving to be a successful operation and I congratulate you on all the hard work and effort you have put into it.

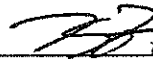
I offer my full support for your proposed Island Harvest expansion in this new local agricultural business which will provide jobs and economic benefits to the Cowichan Valley region. I wish you every success in your future endeavours.

Sincerely,

Graham P. Bruce, MLA
Cowichan-Ladysmith

EXHIBIT "B"

This is Exhibit "B" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.

 RICK TOWSE, Barrister

A commissioner for taking affidavits
For British Columbia



1000 Hutchinson Road
Cobble Hill, BC,
Canada V0R 1L4

Phone (250) 929-8614
Fax (250) 929-8614
Email: info@islandharvest.ca

August 27, 2013

Controlled Drugs Section,
Licences and Permits Division,
Office of Controlled Substances,
Controlled Substances and Tobacco Directorate
Health Canada,
150 Tunney's Pasture Driveway,
Tunney's Pasture, A.L.: 0300B
Ottawa, ON K1A 0K9

**RE: APPLICATION TO BECOME A LICENSED PRODUCER
UNDER THE MARIJUANA FOR MEDICAL PURPOSES REGULATIONS**

To Whom It May Concern,

Our company is applying to the Office of Controlled Substances to become a Licensed Producer (LP) under the *Marijuana for Medical Purposes Regulations* (MMPR).

Enclosed is the completed Health Canada MMPR application form. In addition to the completed application form is an appendix with all related documents pertaining to the application process. Our security clearance document package was mailed under separate cover on July 8, 2013, and received by Health Canada's Office of Controlled Substance on July 11, 2013.

Please let me know if you require additional information.

The best method to contact me is by email: eric.nash@islandharvest.ca

I look forward to hearing from you.

Sincerely,

Eric Nash

A handwritten signature in black ink, appearing to read "Eric Nash", with a long horizontal flourish extending to the right.

Director, Officer, Principal
Island Harvest Inc.
Proposed Senior Person in Charge (Senior PIC)

EXHIBIT "C"

This is Exhibit "C" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


ERIC TAUSCH, BARRISTER

A commissioner for taking affidavits
For British Columbia

From: MMPR-RMFM

Sent: Tuesday, September 03, 2013 12:53 PM

To: eric.nash@islandharvest.ca

Subject: Receipt of Licensed Producer Application under the MMPR

Hello Mr. Nash,

Thank you for your interest in becoming a licensed producer under the *Marihuana for Medical Purposes Regulations* (MMPR). Your application package has been received and it will be reviewed in a timely manner. Please be advised that you will be contacted if and when more information is required to complete the processing of your application.

Your file number is 10-MM0102. Please use this number in every communication with us to facilitate cross-referencing with your application.

If you have any additional questions, please do not hesitate to send us your questions by email at MMPR-RMFM@hc-sc.gc.ca or call us at 1-866-337-7705.

Licences and Permits Division
Office of Controlled Substances
Health Canada



1000 Hutchinson Road
Cobble Hill, BC,
Canada V0R 1L4

Phone (250) 929-8614
Fax (250) 929-8614
Email: info@islandharvest.ca

January 24, 2014

File no. 10-MM0102
RE: OF15-59-1484-34

Jacinthe David, Manager
Controlled Drugs Section, Licences and Permits Division,
Office of Controlled Substances,
Controlled Substances and Tobacco Directorate
Health Canada, 150 Tunney's Pasture Driveway,
Tunney's Pasture, A.L.: 0300B
Ottawa, ON K1A 0K9

Subject: Request to issue "Ready to Build" notice to Island Harvest Inc.

Dear Jacinthe,

Thank you for your letter of December 18th, 2013 requesting additional information pertaining to our Licensed Producer application. I have sent the requested material in regards to Quality Assurance, Physical Security and Record Keeping for your review and approval.

As a proposed Licensed Producer, we are committed to meeting Health Canada's MMPR requirements. This letter is a formal request for a "Ready to Build" letter issued to us so that we can obtain the necessary financing approvals to meet our approaching deadline.

Could you or someone in your department email me a notice to verify that our proposed plan is deemed satisfactory, and that our proposal (if built to the specifications as presented) would meet the requirements of the MMPR?

Could you let me know if this can be done ASAP so that we can move forward? Thank you.

The best method to contact me is by email: eric.nash@islandharvest.ca

I look forward to hearing from you.

Sincerely,

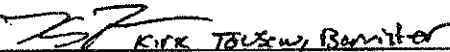
Eric Nash

A handwritten signature in black ink, appearing to read "Eric Nash", is written over the typed name.

Director, Officer, Principal
Island Harvest Inc.
Proposed Senior Person in Charge (Senior PIC)

EXHIBIT "D"


This is Exhibit "D" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


Kirk Tolson, Registrar

A commissioner for taking affidavits
For British Columbia

EXHIBIT "E"

This is Exhibit "E" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


KYLE TAVELAND DERRISTER

A commissioner for taking affidavits
For British Columbia

From: MMPR-RMFM

Sent: Friday, January 24, 2014 9:01 AM

To: Eric Nash

Subject: Re: File No: 10-MM0102 - Additional Information: Security - Division 3

Hello Eric,

Thank you for your interest in becoming a licensed producer under the *Marihuana for Medical Purposes Regulations* (MMPR).

Please be advised that the additional information for your application was received by our office. It will be screened by our office and you will be contacted if more information is required at any point.

There are five steps to the process once your application has been received:

- **Screening**: the application is verified to make sure all relevant information has been provided, and required documents attached. If information is missing, the application may be returned to you.

- **Reviewing**: the application will be reviewed to validate the information and documents provided. Security clearance forms will be sent for processing. Physical security plans will be reviewed and assessed.

- **Ready to build**: Once the application is deemed satisfactory, Health Canada will issue a notice informing the applicant that, if built to the specifications on the proposed plan, the security measures would meet the requirements of the MMPR. Applicants must then build the security measures if this is not already done.

- **Pre-licence inspection**: Upon confirmation from the applicant that the security measures are in place, a pre-licence inspection will be scheduled. Upon completion of the inspection, the applicant must address any deficiencies identified.

- **Issuance**: Once the inspection is deemed satisfactory and that personnel security clearances have been obtained, then the licence will be issued.

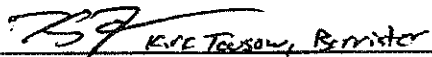
If you are requesting an update on the status of your application to become a Licensed Producer, please note that you will receive a letter from Health Canada if and when any additional information is required to continue processing your application. Thank you for your cooperation.

If you have any additional questions, please do not hesitate to send us your questions by email at MMPR-RMFM@hc-sc.gc.ca or call us at 1-866-337-7705.

Licences and Permits Division
Office of Controlled Substances
Health Canada

EXHIBIT "F"

This is Exhibit "F" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


K. E. Tauson, Registrar

A commissioner for taking affidavits
For British Columbia



Health
Canada

Santé
Canada

Healthy Environments
and Consumer Safety
Branch

Direction générale,
Santé environnementale et
sécurité des consommateurs

Address Locator 0300B
Ottawa ON K1A 0K9

Your file Votre référence

Our file 10-MM0102
OF15-59-1484 -34

2014-02-19

Island Harvest Inc.
c/o Mr. Eric Nash
1000 Hutchison Road
Cobble Hill, BC V0R 1L4

Physical security requirements of your application

Dear Mr. Nash,

We are writing to you regarding your application to become a Licensed Producer under the *Marihuana for Medical Purposes Regulations* (MMPR). Please note that the statements set out in this letter are all subject to verification by Health Canada at a pre-licence inspection, **and are contingent on all key personal identified in your application receiving the security clearance required under the MMPR, which are still in process at this time.**

We have reviewed your application and note from the information and documentation that you have provided to us that your proposal meets the requirements of the quality assurance pre-licensing report and record keeping requirements of the MMPR.

With respect to the security requirements set out in the MMPR our review of your application indicates that if the cultivation and storage requirements are implemented as planned your proposal would be in compliance with Division 3 of the MMPR.

Concerning the vault, cage and electronic security systems proposed in your application, if implemented as planned your proposal would meet the requirements of Health Canada's *Directive on Physical Security Requirements for Controlled Substances* for a security level 5.

This letter is issued on the basis of the information submitted in the application number stated above. Any proposed modifications to the information provided must be submitted to Health Canada; approval must be obtained prior to the modifications being implemented. This includes, but is not limited to, the location of the proposed site and changes to the proposed security measures.

Please inform us when you have completed your security installation and the electronic security is functional. We will arrange for the pre-licence inspection. The inspection will confirm

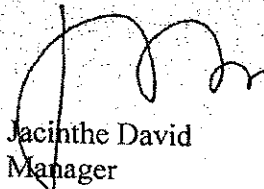
Canada

compliance with all requirements of the MMPR, including the security of the cultivation area and the security of the storage area.

Once a pre-license inspection has been conducted to verify compliance with the requirements under the MMPR and the key personal identified in your application have received the security clearance required under the MMPR a producer's licence will be issued.

If you have any additional questions, you can contact us by email at MMPR-RMFM@hc-sc.gc.ca or call us at 1-866-337-7705.

Yours very truly,



Jacinthe David
Manager
Licences and Permits Division
Office of Controlled Substances
Health Canada

From: MMPR-RMFM

Sent: Monday, February 24, 2014 11:33 AM

To: Eric Nash

Subject: Re: File No: 10-MM0102 - phone call request

Hello,

A ready-to-build was signed for your file today. You should receive a copy of it during today or tomorrow at the latest.

Thanks

If you have any additional questions, please do not hesitate to send us your questions by email at MMPR-RMFM@hc-sc.gc.ca.

Licences and Permits Division
Office of Controlled Substances
Health Canada

EXHIBIT "G"

This is Exhibit "G" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.



A commissioner for taking affidavits
For British Columbia

From: Eric Nash

Sent: Wednesday, May 21, 2014 12:33 PM

To: MMPR-RMFM

Cc: wendy.little@islandharvest.ca

Subject: Re: File No: 10-MM0102 - security clearance confirmation request

Re: Security Clearance – File # 10-MM0102

Hello,

I am inquiring in regards to our MMPR security clearance confirmation.

We submitted our security clearance forms with our licensed producer application in August 2013 (see attached cover letter) and we recently received our ready-to-build letter in February 2014.

Our facility is nearing completion and we will soon be ready for our pre-license inspection.

Could you please confirm that our security clearance documents have been processed and approved. Thank you.

We look forward to hearing from you soon.


Best regards,
Eric Nash

Phone: 250-929-8614
Director, Officer, Principal
Island Harvest Inc.
Proposed Senior Person in Charge (Senior PIC)

cc. Wendy Little, Proposed Alternate Responsible Person In Charge (A/RPIC)

EXHIBIT "H"

This is Exhibit "H" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


K. D. Tasson, District

A commissioner for taking affidavits
For British Columbia

From: MMPR-RMFM
Sent: Tuesday, July 15, 2014 8:04 AM
To: eric.nash@islandharvest.ca
Subject: 10-MM0102 - Island Harvest Inc.

Hello Mr. Nash,

It has to come to our attention that you have been corresponding with other Health Canada officials regarding your application to become a licensed producer under the *Marihuana for Medical Purposes Regulations (MMPR)*. Please note that the MMPR inbox should be used for all communications regarding your application.

As discussed yesterday, as of July 1, 2014 a minimum security level 7 is required for an application to be considered. Additional information will be provided to you on this in the coming weeks.

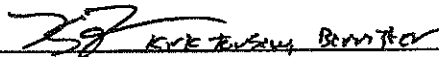
Information on the physical security directive can be found on the Health Canada website at: http://www.hc-sc.gc.ca/hc-ps/pubs/prekurs/dealers-distrib/phys_securit_directive/index-eng.php.

If you have any additional questions, please do not hesitate to send us your questions by email at MMPR-RMFM@hc-sc.gc.ca or call us at 1-866-337-7705.

Licences and Permits Division
Office of Controlled Substances
Health Canada

EXHIBIT "I"

This is Exhibit "I" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.



A commissioner for taking affidavits
For British Columbia

From: MMPR-RMFM

Sent: Friday, July 18, 2014 9:06 AM

To: Eric Nash

Subject: Security Requirements

Hello Mr. Nash,

Thank you for your continued interest in becoming a licensed producer under the *Marihuana for Medical Purposes Regulations* (MMPR).

This letter is to inform you that applicants under the MMPR must now meet, at a minimum, a level 7 under the Physical Security Directive for their security requirements.

We are contacting you today because your application currently does not meet this requirement.

In order for the processing of your application to continue, you must submit a revised physical security proposal showing how you will meet, at a minimum a level 7.

Information on the requirements for a level 7 and up can be found on the Health Canada website at:

http://www.hc-sc.gc.ca/hc-ps/pubs/precurs/dealers-distrib/phys_securedirective/index-eng.php

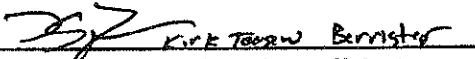
If you intend to submit to us a revised security proposal, please let us know by August 22, 2014.

If you have any additional questions, please do not hesitate to send us your questions by email at MMPR-RMFM@hc-sc.gc.ca or call us at 1-866-337-7705.

Licences and Permits Division
Office of Controlled Substances
Health Canada

EXHIBIT "J"

This is Exhibit "J" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


Kirk Turner Barrister

A commissioner for taking affidavits
For British Columbia

From: Eric Nash

Sent: Friday, July 18, 2014 1:30 PM

To: George Da Pont - Deputy Minister

Cc: Francine E Morin ; Hilary Geller ; Jacinthe David ; Jean Crowder MP ; jean.crowder.c1@parl.gc.ca ; Melissa Smith ; Robert Browne ; Sarah Baxter ; Sarah Wright-Gilbert ; Theresa Schopf ; Todd Cain ; Wendy D. Little ; Alistair MacGregor ; Chris Rose

Subject: George Da Pont - Deputy Minister - Assistance Request re: Marihuana for Medical Purposes Regulations (MMPR) - File No. 10-MM0102

George Da Pont - Deputy Minister
Health Canada - Deputy Minister's Office
70 Colombine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9 Canada

Friday, July 18, 2014

Dear Mr. Da Pont,

I am writing to ask for your assistance in regards to regulatory delays with Health Canada's file processing for our company to become a licenced Producer under the *Marihuana for Medical Purposes Regulations* (MMPR). In August 2013, our company Island Harvest Inc. applied to Health Canada for Licenced Producer status under the new MMPR.

On February 19th, 2014 our company was issued a Level 5 security directive approved "Ready to Build" letter (OF15-59-1484-34) from Health Canada deeming that our application has fulfilled the requirements of the MMPR. The approval letters states:

"We have reviewed your application and note from the information and documentation that you have provided to us that your proposal meets the requirements of the quality assurance pre-licensing report and record keeping requirements of the MMPR... Concerning the vault, cage and electronic security systems proposed in your application, if implemented as planned your proposal would meet the requirements of Health Canada's Directive on Physical Security Requirements for Controlled Substances for a security level 5... Please inform us when you have completed your security installation and the electronic security is functional. We will arrange for the per-licence inspection." (see attached letter).

In recent correspondence and phone calls from Health Canada, our company was advised that there are coming changes to the security directive, eliminating the security level 5 and 6 options for Licenced Producers, and making Level 7 the minimum new requirement for compliance. I understand this, and our facility currently meets the Level 7 requirements for the 3 components of electronic access control, video and intrusion detection. The other component of security is the storage of dried product, in the form of a safe, vault or cage. However, for several months without any product grown, dried ready for storage, the storage component at level 7 security will not be required.

In regards to the newly proposed change in the security directive to level 7, approval on our security upgrade has been granted to us by Health Canada in prior recent correspondence as follows: "We would like you to note that if the inspection is successful and you are granted an MMAP licence, this will be contingent on an upgrade to a minimum security level 7 within the next 12 months."

From a telephone conversation I had this afternoon with Bridget Lucke, Chris Rose and Jacinthe David of Health Canada, I understand that currently there are ongoing discussions at Health Canada in coming to a reasonable solution for those approved at the current Level 5 and 6, who have spent months of hard work and significant financial resources to comply with the security directive at their previously approved level.

As we continue to act in good faith as a proposed licenced producer in meeting the regulatory requirements of the MMAP, we now ask for your assistance in this extenuating circumstance by approving the inspection and grandfathering of our level 5 facility, with our agreement to upgrade to the new level 7 security requirements within a one year time from the date of our MMAP production licencing.

I believe that this would be a fair, just and reasonable decision and a good solution to those Level 5 and 6 production applicants in a similar situation, considering the circumstances. We could then get licencing approval, start our seedlings for our crop production, and in several months, when we have product ready for the storage component, our security level 7 requirement will be fulfilled, and ready for compliance under the new security directive guidelines.

I look forward to hearing from you and Health Canada soon in regard to a decision in coming to a mutually beneficial solution to these regulatory changes.

Best regards,
Eric Nash

Director, Officer, Principal
Island Harvest Inc.
Proposed Senior Person in Charge (Senior PIC)

cc: Wendy D. Little - proposed A/RPIC, Hilary Geller, Sarah Wright-Gilbert, Sarah Baxter, Todd Cain, Jean Crowder, Jacinthe David, Chris Rose, Theresa Schopf, MMAP-PAMM, file

EXHIBIT "K"

This is Exhibit "K" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.

 ERIC TOLSON Barrister

A commissioner for taking affidavits
For British Columbia

From: Eric Nash

Sent: Friday, November 07, 2014 2:47 PM

To: George Da Pont - Deputy Minister

Cc: Francine E Morin ; Justin Trudeau MP ; Elizabeth May MP ; Thomas Mulcair MP ; Wendy Little ; 'Eric Nash'

Subject: Island Harvest Inc. application- Health Canada's MMPR regulatory delay re: File no. 10-MM0102

George Da Pont - Deputy Minister
Health Canada - Deputy Minister's Office
70 Colombine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9 Canada

Friday, November 7, 2014

Dear Deputy Minister Da Pont,

I am writing to you with very serious concerns about irregularities, deficiencies and contradictions regarding the regulatory process and policy framework with application file processing at Health Canada's Office of Controlled Substances under the *Marihuana for Medical Purposes Regulations* (MMPR).

Here is a summary of what has occurred to date in regards to our company's MMPR licensed production application with Health Canada:

In August 2013 our company Island Harvest Inc. applied to Health Canada under the *Marihuana for Medical Purposes Regulations* (MMPR). Over the past year, since our company applied to obtain Licensed Producer (LP) status, we have been thoroughly and rigorously screened and reviewed by Health Canada.

On November 21, 2013 I received a phone call from Health Canada's Aaron Bergbusch advising me that the Licences and Permits Division at Health Canada's Office of Controlled Substances would like to get Island Harvest Inc. licensed as soon as possible.

Mr. Bergbusch informed me that Health Canada would like to expedite the MMPR licencing process and will inspect and issue Island Harvest a MMPR license. The prerequisite for the pre-license inspection is that our access control, intrusion detection and video monitoring system must be installed and up and running for the inspection to occur. In this regard, the Island Harvest facility has been ready for inspection for many months.

On February 24th 2014, Island Harvest was issued a "Ready to Build" approval letter from Health Canada (OF15-59-1484-34) deeming that our application is satisfactory and meets the requirements of the MMPR. The February 24th letter stated "We have reviewed your application and note from the information you have provided to us that your proposal meets the requirements of the quality assurance pre-licensing report and record keeping requirements of the MMPR."

In the February 19th, 2014 "Ready to Build" letter from Health Canada (attached pdf), we were requested to "Please inform us when you have completed your security installation and the electronic security is functional. We will arrange for the pre-licence inspection."

I noted from previous January 24th, 2014 email correspondence from Health Canada (see attached HC-IH-Lic-Applic-Process-Jan24.pdf), "Upon confirmation from the applicant that the security measures are in place, a pre-licence application will be scheduled. Upon completion of the inspection, the applicant must address any deficiencies identified."

On May 28th 2014, as previously instructed, I wrote to Health Canada advising that Island Harvest Inc. was ready for the pre-licence inspection, having satisfied and fulfilled the conditions of the Level 5 Physical Security Directive as noted in the February 24th "Ready-to-Build" approval letter.

At this point in May 2014, Island Harvest's application was approved to the pre-licensing inspection phase, and we subsequently requested on several occasions that an inspection be scheduled so that no further delays were incurred.

Instead of receiving our scheduled inspection date, on June 5th, 2014 Health Canada emailed a letter to me with a series of questions requesting additional information primarily regarding quality assurance and record keeping. This request was completely unexpected and disconcerting, as we had been previously informed that our *Quality Assurance Pre-Licensing Report* and *Record Keeping* application requirements had been satisfactorily met. However we responded to these questions in depth and increasingly detailed information. We then continued to receive a succession of further "Validation Questions" on June 23rd, June 25th and July 2nd.

Over the past year, I've had ongoing contact with Health Canada's Jacinthe David (Manager) in regards to Island Harvest's file, as she signed and sent us our "Ready-to-Build" approval letter for our level 5 facility in February. As instructed, Island Harvest has had the specified security measures in place since May 2014 and we've been waiting for our pre-licence inspection since then.

On Monday, July 14, I phoned and spoke with Ms. Jacinthe David and asked her again for the date of our scheduled pre-licensing inspection.

In my July 14th phone conversation with Ms. David, I heard a most unexpected and disturbing response. She replied to me that "We've been avoiding your inspection because we're upgrading everyone to a level 7 security." She also added that Health Canada will not inspect a Level 5 facility.

After a one year application file processing time, Monday, July 14, 2014 was the first time our company was advised that the Licences and Permits Division will not inspect our Health Canada pre-approved level 5 facility. Island Harvest was issued a signed Level 5 "Ready to Build" approval letter by Health Canada and our company built our facility to the exact standards of this directive at significant operational expense under a long-term lease.

On June 23rd, June 25th and July 2nd, we received three separate notices from Health Canada advising us that after our inspection, we have 12 months to complete an upgrade to a Physical Security Directive Level 7 for our product storage:

"We would like you to note that if the inspection is successful and you are granted an MMPR licence, this will be contingent on an upgrade to a minimum security level 7 vault within the next 12 months."

On July 18th, 2014, in contradiction to the three previous notices, we received another notice from Health Canada informing Island Harvest that our facility does not meet the security requirements, and instead of having 12 months to complete the upgrade, we must immediately comply with their policy change:

"This letter is to inform you that applicants under the MMPR must now meet, at a minimum, a level 7 under the Physical Security Directive for their security requirements. We are contacting you today because your application currently does not meet this requirement."

We are now approaching an application file processing time of almost eighteen months. Over this time we have diligently and conscientiously followed Health Canada's Marihuana for Medical Purposes Regulations (MMPR) procedural and application process instructions.

We have Health Canada's verification that we successfully attained our Security Clearances for the company's key personnel and acknowledgment that we have fulfilled all of the application requirements. We've engaged with some of Canada's most proficient experts in the Security and Quality Assurance components of our application and have invested substantial financial resources to this project. After many years of hard work, the current situation is both perplexing and disheartening. Our facility security measures have been in place for many months, and we are still waiting for our pre-license inspection by Health Canada.

As part of our commitment to quality assurance and the quality control component of our application, Island Harvest retained Margaret Daskis, one of Canada's most highly-experienced and well-respected national award-winning QC/QA experts as our assigned Quality Assurance person. With over 30 years' experience and technical expertise in the field, and having developed numerous Standard Operating Procedures, Policy Manuals, conducting recalls and scientific operating and testing procedures throughout Canada, Margaret held the top Quality Assurance and Quality Control position at Nalley's Canada Ltd. As the "Director of Quality Assurance and Research & Development" for over a decade, no other position within Nalley's Canada usurped her Quality Assurance authority.

In respect to the security portion of our application, our security system was designed, built and installed by one of Canada's leading award-winning national security firms. A few of our security firm's clients are notable organizations such as Chevron, Petrocan, Shell Oil, Imperial Oil, U.S. Department of Justice and Homeland Security as well as many Canadian government offices and institutions including the R.C.M.P. In respect to our company's Record-Keeping methods, our system is impeccable, and has previously been approved for the MMPR by Health Canada's comprehensive LP review process.

After receiving a Level 5 "Ready-to-Build" approval letter for our facility from Health Canada in February 2014, and after being intentionally delayed and ignored for months by Health Canada's admission of using tactics such as avoidance, I find the lack of honesty, integrity and ethics in Health Canada's administration of our file both astounding and appalling. We have acted with complete trust, accountability and good faith in diligently following all the governmental guidelines, regulations and requests put forward to us by Health Canada and the Licences and Permits Division throughout the entire MMPR application process.

While we have acted in good faith, I feel that we have been treated with disingenuous and insincere falsity. I believe that Health Canada has a responsibility and duty to act in good faith, with the highest of moral and ethical standards. With the handling of our company's MMPR file, this has most assuredly not occurred, and there have been many very serious oversights, misleading falsehoods, and Health Canada has broken the most sacred and ethical trust in public accountability.

These broken promises and misleading commitments from Health Canada are unbelievably unsettling and disturbing. The "Ready-to-Build" approval letter from Health Canada was the turning point for our complete financial commitment to this business venture. No matter how I look at this situation, it appears fundamentally wrong to me, and every professional I have spoken to about this wholeheartedly agrees. I have grave concerns that any signed letter directive from Health Canada means absolutely nothing, Health Canada cannot be trusted to adhere to previous commitments made, and there is no assurance that whatever Health Canada writes or presents to Island Harvest or any other company for that matter, can be interpreted as anything other than false words.

On October 9th, 2014 Health Canada received Island Harvest's plan for upgrading to their newly requested Level 7 product storage security directive. We again requested our pre-license inspection. Since that date I have heard nothing, and I sincerely doubt that we will receive anything but continued stall tactics, additional complications to delay our file, and more roadblocks to prevent our company from moving forward in this new industry. Health Canada is clearly moving the regulatory goalposts of the MMPR to obfuscate the application process to limit businesses entering the market, which has nothing to do with their supposed mandate of ensuring public health, safety or security.

Health Canada openly admits, allows and condones dozens of unlicensed organizations across Canada to distribute medical cannabis to the Canadian public, while at the same time deliberately blocks and prevents the licensing of legitimate companies and businesses from operating with ethics, accountability, principles of honesty, integrity, security, health and safety. I am astounded and appalled at the disingenuous behaviour of Health Canada with the unimaginably slow file processing times of over one year, with Island Harvest's application now approaching 18 months, with no foreseeable end in sight.

I have attached 3 documents corresponding to our file:

- 1.) Island Harvest's February 2014 "Ready-to-Build" letter from Health Canada
- 2.) A January 24th, 2014 email to Island Harvest from Health Canada outlining the MMPR application process.
- 3.) Several letters of long-term local government support for Island Harvest

For reference and communication, Island Harvest's MMPR application file number with Health Canada is 10-MM0102.

I thank you for reviewing Island Harvest's application with Health Canada's Office of Controlled Substance's Licences and Permits Division, and look forward to your expeditious resolution of this matter.

I can be reached via email at eric.nash@islandharvest.ca

Best regards,
Eric Nash

Director, Officer, Principal
Proposed Senior Person in Charge (Senior PIC)
Island Harvest Inc.
Member – *The Canadian Medical Cannabis Industry Association (CMCIA)*
Phone: 778-422-2837

cc: Wendy D. Little – Proposed A/RPIC, Eric Nash, Francine E. Morin, IH file

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EXHIBIT "L"

This is Exhibit "L" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.


Eric Tansley, Barrister

A commissioner for taking affidavits
For British Columbia

From: George Da Pont

Sent: Saturday, November 08, 2014 2:14 PM

To: Eric Nash

Cc: Hilary Geller ; Eric Costen

Subject: Re: Island Harvest Inc. application- Health Canada's MMPR regulatory delay
re: File no. 10-MM0102

This is to acknowledge receipt of your e-mail. I will look into the matter.

Sent from my BlackBerry 10 smartphone on the Rogers network.

EXHIBIT "M"

This is Exhibit "M" referred to in the Affidavit of Eric John MacArthur Nash sworn before me at Duncan, BC this 8th day of January, 2015.

 KYLE TOUSEY, BARRISTER

A commissioner for taking affidavits
For British Columbia

From: jean.crowder.c1@parl.gc.ca

Sent: Tuesday, December 09, 2014 11:24 AM

To: eric.nash@islandharvest.ca

Subject: RE: Follow-up from Jean Crowder's office - Island Harvest's MPR application and regulatory delay

Hi Eric,

The minister's office has informed me that they have no new information to provide and cannot provide any information until you hear directly from the department. Coming from the minister's office, this answer is simply not acceptable. I have responded and asked for some ministerial accountability on behalf of the department in question.

I hope to hear back soon.

Sincerely,

ALISTAIR MACGREGOR

Constituency Assistant

Jean Crowder, MP, Nanaimo-Cowichan

(TEL) 250-746-2355 | (TOLL FREE) 1-866-609-9998 | (FAX) 250-746-2354
www.jeancrowder.ca

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