



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

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

September 18, 2015

In Good Health, Inc.
Mr. David Noble, CEO
1200 West Chestnut St.
Brockton, MA 02301

Re: Request for an Expansion of Temporary Waiver

Dear Mr. Noble:

On September 5, 2015, In Good Health, Inc. ("IGH") submitted a written request to expand the waiver dated August 31, 2015 (the "Waiver"), which waived 105 CMR 725.105(C)(2)(a) as it applies to heavy metals and pesticides, and 105 CMR 725.105(E)(2)(g), labeling requirements for finished plant material, subject to the conditions within the Waiver. The September 5 request seeks to expand the Waiver to apply to cannabis concentrate and also to waive the requirements of 105 CMR 725.105(E)(3)(i), labeling requirements for marijuana-infused products (MIPs).

In the September 5 expansion request, you represented that Massachusetts laboratories were currently unable to test to the levels required by the Department. You have submitted testing reports from the laboratory used by IGH that supports your representation.

I find that compliance would cause undue hardship to IGH and patients, that IGH will institute compensating features acceptable to the Department of Public Health (the "Department") and that with those compensating features, non-compliance does not jeopardize the health or safety of any patient or the public. IGH's September 5, 2015 request for an expansion of the Waiver from 105 CMR 725.105(C)(2)(a), only as it applies to heavy metals and pesticides, as well as the labeling requirements in 105 CMR 725.105(E)(3)(i) so as to allow the dispensing of cannabis concentrate is granted effective as of the day of this letter for the remaining of the Waiver Term as described in August 31, 2015 letter. This extended waiver is subject to the conditions set forth below:

1. For the remainder of the Waiver Term, or until such time that IGH has demonstrated to the Department's satisfaction that it can fully comply with the *Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Marijuana Dispensaries* and *Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries*

(collectively, the "Protocols"), whichever occurs earlier, it may only dispense a maximum of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate (1 gram of cannabis concentrate = 5.16 grams of finished plant material), or a combination of both that would not exceed a total of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate, and must supply each qualifying patient or caregiver with instructions that for finished plant material, a maximum of 2 grams may be consumed per day, and for cannabis concentrate, a maximum of 1.13 grams be consumed per day;

2. During the Waiver Term, IGH shall continue to conduct testing in compliance with the Protocols for finished plant material and cannabis concentrate for all substances listed in 105 CMR 725.105(C)(2)(a), including heavy metals and pesticides, and submit the results to the Department;
3. During the Waiver Term, IGH shall take all necessary steps to ensure that the presence of heavy metals in finished plant material and cannabis concentrate is as minimal as possible, but shall not be required to meet the levels specified in Exhibit 4 of Section 7 of the *Protocol for Sampling and Analysis of Finished Medical Marijuana and Marijuana-Infused Product for Massachusetts Registered Marijuana Dispensaries*;
4. Consistent with IGH's representation in its request that it does not use the plant-growth regulators and pesticides identified in the Protocol, IGH shall not use any of the plant-growth regulators and pesticides identified in the Protocol during the Waiver Term;
5. During the Waiver Term, IGH shall be subject to increased inspections to ensure compliance with the conditions of this waiver, including requests for additional testing and information regarding the testing capabilities of any independent laboratory selected for testing by IGH;
6. IGH must maintain records available for inspection by the Department that it only dispenses a maximum of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate (1 gram of cannabis concentrate = 5.16 grams of finished plant material), or a combination of both that would not exceed a total of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate, and must supply each qualifying patient or caregiver with instructions that for finished plant material, a maximum of 2 grams may be consumed per day, and for cannabis concentrate, a maximum of 1.13 grams be consumed per day;
7. Labels for all marijuana finished plant material and cannabis concentrate produced during the Waiver Term shall disclose that product may not meet the established standards for heavy metals and pesticides:

"WARNING: This product may not meet the established standards for heavy metals and pesticides."

8. The Department reserves the right to revoke or modify this waiver at any time should it determine that IGH, or any of its dispensary agents, fail to comply with the terms and conditions of the waiver, or if the Department finds that the waiver no longer serves the

interests of the public health or safety, including in the event that the Department develops updated Protocols pursuant to 105 CMR 725.105(C)(2).

The Department anticipates that IGH will work expeditiously to resolve the issues that have led to the request for the Waiver, as expanded. If, however, IGH determines it cannot do so within the Waiver Term, a request for any additional waiver must be received by the Department 14 days prior to the expiration of the current Waiver. Please contact RMDcompliance@state.ma.us with any questions regarding this Waiver.

Sincerely,

A handwritten signature in blue ink, appearing to read 'MBH', is positioned above the typed name.

Monica Bharel, MD, MPH
Commissioner
Massachusetts Department of Public Health