



Indiana State
Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

CERTIFIED MAIL #7002-2410-0000-1701-6357

June 16, 2014

George Donaldson
Donaldson's Finer Chocolates
600 S. State Road 39 South
Lebanon, IN 46052

Re: Variance Request Dated October 18, 2013, # 642013 and Section 171, Preventing Contamination from Hands

Order to Grant a Variance

On October 18, 2013, this office received a request for Donaldson's Finer Chocolates, 600 S. State Road 39 South, Lebanon, IN 46052 to vary section 171 of 410 IAC 7-24, "Retail Food Establishment Sanitation Requirements," relating to bare-hand contact with ready-to-eat food. A letter requesting additional information was sent from this office on April 30, 2014. On May 30, 2014, a letter was received in response which included additional information and attachments.

You are hereby notified that based on the recommendation of the Indiana State Department of Health (ISDH), Food Protection Program, and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be approved to George Donaldson, Owner, Donaldson's Finer Chocolates.

This **VARIANCE APPROVAL** is based on the following criteria:

- The following Indiana location:

600 S. State Road 39 South, Lebanon, IN 46052
- The initial application along with the materials submitted on May 30, 2014 shall be the regulatory basis for determining compliance with this variance relating to the bare-hand contact process.
- The Department shall be notified by company agents of Donaldson's Finer Chocolates of any substantive changes in the product manufacturing process.
- The facility person-in-charge shall allow random surveillance sampling by the regulatory authority of hand-dipped candy for laboratory testing at any time to verify that the submitted plan is being properly followed.



- The recall process submitted on May 30, 2014 shall be utilized in the event a Donaldson's Finer Chocolates product, or product ingredient, becomes associated with a food safety hazard.
- A copy of this approval letter, along with a copy of the materials submitted in the letter of May 30, 2014, must be kept onsite in the establishment at all times and readily available for review by local or state health department personnel;
- A Certified Food Handler shall be on duty at all times while hand-dipping is occurring at this location to properly oversee all food safety requirements.
- A manager-on-duty (MOD) shall reinforce training on the submitted employee health policy at least once each calendar year.
- This variance does not extend to locations not listed above. There shall be no other food establishments in Indiana conducting this process by this company unless explicitly approved by the Indiana State Department of Health. The establishment must request and receive approval from the ISDH Food Protection Program least thirty (30) days prior to adding new Indiana locations to this variance.
- Donaldson's Finer Chocolates shall comply in all aspects of the 410 IAC 7-24, as determined by the ISDH and/or local health department, except as stated above. Any change to the management, structure of the operations, or procedures could invalidate this variance Order
- This variance Order is limited to Donaldson's Finer Chocolates and the current scope of existing operations. This variance Order is not transferable to a new owner.
- This variance Order is limited to being in compliance with all other applicable state and local regulations.
- Donaldson's Finer Chocolates agrees to allow copying and/or transmittal of submitted proprietary and/or copyrighted material for regulatory purposes.
- Any provisions not adhered to may result in the revocation of this order.

If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §40-21.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:

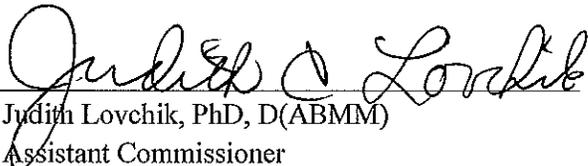
- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

Your request for review or stay of effectiveness must be filed in writing with the State Health Commissioner, 2 North Meridian Street, Indianapolis, Indiana 46204, on or before July 4, 2014. If no request for review or stay of effectiveness is filed by July 4, 2014, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA THIS 16th DAY OF JUNE 2014.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY APPROVE A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

WILLIAM C. VAN NESS II, M.D.
STATE HEALTH COMMISSIONER

By: 
Judith Lovchik, PhD, D(ABMM)
Assistant Commissioner
Public Health Protection and Laboratory Services Commission

cc: ISDH Executive Board
ISDH Food Protection Staff
ISDH Office of Legal Affairs
Boone County Health Department