



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

IN RE THE MATTER OF:

Joseph Hernandez, Executive Chef
Memorial Hospital of South Bend
615 North Michigan Avenue
South Bend, IN 46601

Re: Variance Request, Initially submitted Dec 15, 2010, revised and resubmitted October 10, 2011;
and Section 195, Reduced Oxygen Packaging (ROP); criteria

Order to Approve a Variance

You are hereby notified that based on the recommendation of the Food Protection Program, Indiana State Department of Health (ISDH), 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 Memorial Hospital of South Bend (MHSB), 615 North Michigan Avenue, South Bend, IN 46601. These findings for this order were determined by review of several revisions of supporting materials submitted December 15, 2010 through November 18, 2011, including an on-site evaluation conducted by representatives of ISDH on April 25, 2011, and training materials submitted through November 18, 2011.

Order

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

- The HACCP Plan and system for the affected product does not change from what has been submitted;
- The list of reduced oxygen packaged (ROP) food items submitted in the version of materials dated October 10, 2011 does not change without prior authorization from this agency;
- ROP food items produced under this approval may only be used on the MHSB campus and may not be used, sold, or otherwise transferred to any other person outside of MHSB administrative control.
- After a date one year from approval and not more than 13 months, examples of actual, completed forms that were created throughout the year shall be submitted to the ISDH, Food Protection Program Director for review. These completed records shall consist of the forms submitted in the materials of October 10, 2011. No modifications of this variance shall be approved prior to this review.

- MHSB and Maverick Precision Temperature Cooking Systems agree to allow copying/distribution of their materials for regulatory purposes.
- A Certified Food Handler as defined in 401 IAC 7-22 -7 shall be present during periods when food is being sealed in ROP bags.
- All other provisions provided in law shall be complied with at all times; and
- A copy of this order, the application, and a copy of related, submitted materials, including HACCP Plan information & charts, SOPs, and completed forms, shall be maintained and made available to regulatory personnel during inspections.

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:

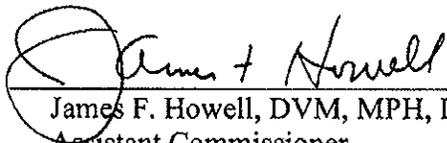
- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

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 January 1, 2012. If no request for review or stay of effectiveness is filed by January 1, 2012, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA THIS 14TH DAY OF DECEMBER 2011.

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.

GREGORY N. LARKIN, M.D.
STATE HEALTH COMMISSIONER

By: 
James F. Howell, DVM, MPH, DACVMP
Assistant Commissioner
Public Health and Preparedness Commission

cc: ISDH Food Protection Staff
ISDH Office of Legal Affairs
ISDH Acute Care, Lynnette Smith
St. Joseph County Health Department