United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Lawrence District Office
4920 Bob Billings Parkway
Lawrence, KS 66049-3855

October 23, 2007

Mr. David Ripley-Plant Manager
ConAgra Foods, Inc.
Est. 01059 M/00009 P
200 N. Banquet Drive
Marshall, MO 65340

NOTICE OF INTENDED ENFORCEMENT

Dear Mr. Ripley:

This serves as official notification by the Food Safety and Inspection Service (FSIS) of our intent to withhold the marks of inspection and suspend the assignment of inspection program personnel at ConAgra Foods, Inc., 200 N. Banquet Drive, Marshall, Missouri 65340 as per 9 CFR 500.4 (Rules of Practice).

Background/Authority

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provides that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. These Acts give FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products, or poultry products, to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that products are adulterated and provide definitions for the term "adulterated." Furthermore, the Act provides FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. They also give FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records.

When the sanitary conditions of a facility are not properly maintained, FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

Under the authorities of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR Parts 416 and Parts 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (9 CFR Part 500). The Rules of Practice describe the types of enforcement action that FSIS may take and include procedures for taking a withholding action and or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of federal inspection.

Findings/Basis for Action

The following information is provided to support this notification of intended enforcement for your facility:

FSIS Enforcement, Investigations, and Analysis Officers (EIAO) conducted a Food Safety Assessment (FSA), beginning on October 9, 2007, and ending on October 23, 2007, at your establishment. This FSA was initiated at the direction of the Lawrence District Office, to verify your establishment's compliance with 9 CFR 417 and 416.

This assessment revealed that your establishment failed to implement and maintain an adequate HACCP system, and Sanitation Standard Operating Procedures (SSOP's) to meet the requirements of 9 CFR 417 and 416 and to ensure food safety.

9 CFR 417 – HACCP

Hazard Analysis (9 CFR 417.2(a)(1) and 417.5(a)(1)):

According to 9 CFR 417.2(a)(1) "Every *official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards."* In addition, 9 CFR 417.5(a)(1) requires that "*The establishment shall maintain the following records documenting the establishment's HACCP plan: The written hazard analysis prescribed in 417.2(a) of this part, including all supporting documentation.*"

1. In your hazard analysis, you have acknowledged that vegetative pathogens are a potential biological hazard in the ingredients that you receive and have defined that this includes *Listeria monocytogenes, Salmonella,* and *E. coli* O157:H7. You have determined that a potential biological hazard (vegetative and spore forming pathogens, rodents, insects) is not reasonably likely to occur at steps for receiving ingredients in your hazard analyses for your pot pie line, dinner lines, Dake line and skillet line. This includes but is not limited to when receiving ingredients for slicing/chipping/dicing (meat/poultry), batching and blending, and dough mixing for your pot pies. Your basis for this decision states that "Raw materials received are evaluated for adulteration, contamination and temperature (if applicable) at receipt. Unacceptable conditions (trailer, container, or product) are cause for rejection. Suppliers are required to have a Supplier Letter of Guarantee on file with ConAgra Corporate Purchasing group."

   Your establishment provided documents describing the specifications for vegetables (potatoes, peas, carrots) that you use in your pot pies. These documents include microbiological requirements for *E. coli, Salmonella and Listeria.* Your establishment said that they do not request documentation from your suppliers on whether the products that you receive have been tested to determine if they are meeting your requirements. Your microbiology sampling (PP-13) for ingredients includes sampling incoming ingredients for TPC, Coliform, yeast and mold, but does not include sampling for pathogens. You did not provide supporting documentation to demonstrate a correlation between TPC, Coliform, yeast and mold counts to the probability of these ingredients being contaminated with *Salmonella.* The documentation that you have provided does not support your decision that vegetative pathogens including *salmonella* are not reasonably likely to occur when receiving ingredients in each of your processes. Therefore, you have failed to meet the requirements of 9 CFR 417.5(a)(1).

   In addition, you included a document titled "Scientific Bases and Justifications associated with CCP's" in the HACCP plan for your pot pie line which states that "The pot pie contains components other than the fully cooked meat and gravy portions that may present a biological hazard" and "There is no processing cooking step to eliminate vegetative pathogens that may then be line blended with the fully cooked meat and gravy. Lethality is addressed through the handling and cooking instructions on the finished product

package". Your documentation for the Dake line, dinner line and skillet/crock pot line included similar statements indicating that lethality is addressed through the handling and cooking instructions on the finished product package.

The labels on your Banquet pot pies clearly state on the front panel "READY IN 4 minutes MICROWAVABLE", even though the cooking directions on the back of the label requires more time in a low wattage microwave with a three minute stand time. In addition, the documentation that you provided states that "Standing time is an important component of achieving the target temperature of ≥160° F." The labels on other store brands also indicate that they are ready in four minutes. The labels on your Great Value pot pie include similar cooking instructions on the back panel, but states "Microwave 6 minutes" on the front. Your validation records did not explain why the labels would indicate four minutes on the front of some brands of product and six minutes on the front of the Great Value brand. Your validation documentation did not indicate if you had taken into consideration how the consumer is likely to interpret the cooking instructions or if the consumer will actually prepare the product according to the instructions under normal conditions of use, especially with the statements on the front of the packages which do not reflect the need to let the products stand after heating.

The cooking directions on the pot pie labels include four minutes in a "Medium OR High Wattage Microwave" and six minutes in a "Low Wattage Microwave". However, your directions do not indicate what is considered to be a high, medium or low watt microwave. Again, your validation documentation did not indicate if you had considered how the consumer may interpret the cooking directions or if the consumer will actually prepare the product according to the directions under normal conditions of use, especially if they did not know whether they were using a high, medium or low wattage microwave.

Your establishment has not provided documentation to support that some of the temperatures reported in your cooking instruction validation documentation for frozen dinners will provide an adequate lethality.

For example, in some of your Banquet meals the chicken fingers only reached a temperature of ≥127° F, the BBQ chicken reached a temperature of ≥141° F and the pork only reached a temperature of ≥142° F. You indicated that these meat/poultry are fully cooked components. However, they are packaged with other ingredients that are not fully cooked and your documentation did not address cross contamination between these ingredients and whether these temperatures will provide an adequate lethality if cross contamination occurs.

In addition, you validation documentation indicates that the corn in your Banquet Chicken Fried Beef Steak dinner only reached ≥139° F. Your establishment has not provided documentation to support whether this temperature will provide an adequate lethality.

As another example, your validation documentation indicates that in the GE large electric conventional oven the pudding in your Kid Cuisine Chicken Breast Nugget meal only reached 142° F with a heating time of 18 minutes. Your establishment has not provided documentation to support whether this temperature will provide an adequate lethality.

The documentation provided by the establishment does not support that lethality is addressed through the handling and cooking instructions on the finished product package as stated in your HACCP records titled "Scientific Bases and Justifications associated with CCP's". Therefore, you have failed to meet the requirements of 9 CFR 417.5(a)(1).

By failing to provide documentation to support the decision that a biological hazard including *Salmonella* is not reasonably likely to occur when receiving ingredients for your pot pies and that lethality is addressed through the handling and cooking instructions on the finished product package. Your establishment has failed to demonstrate

that the biological hazard of vegetative pathogens including *Salmonell*a are not reasonably likely to occur and will not affect the safety of the products for human consumption. This precludes FSIS from determining that the food safety hazards are being controlled and that the products are not adulterated.

Salmonella can cause salmonellosis, one of the most common bacterial foodborne illnesses. *Salmonella* infections can be life threatening, especially to those with weak immune systems, such as infants, the elderly and persons with HIV infection or undergoing chemotherapy. The most common manifestations of salmonellosis are diarrhea, abdominal cramps, and fever within eight to 72 hours. Additional symptoms may be chills, headache, nausea and vomiting that can last up to seven days.

Corrective Actions 9 CFR 417.2(c)(5) and 417.3:

According to 9 CFR 417.3, "*The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective actions, to ensure: 1. The cause of the deviation is identified and eliminated; 2. The CCP will be under control after the corrective action is taken;3. Measures to prevent a recurrence are established; and 4. No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*"

2. Your monitoring records dated 7/20/07 for CCP-2 on their fryer line indicates that the product temperature was 73° at 10:40 and again at 10:50. The record for the 10:40 check indicates that the product was taken to the freezer. The record for the 10:50 check indicates that the product was taken to the production line. However, your records do not indicate that you continued to monitor these products to determine if your critical limit in your HACCP plan was met for this CCP, which requires that the product be cooled from 130° F to 80° F within 1.5 hours and 80° F to 40° F within 5 hours. Your record review documentation for this CCP was signed indicating that establishment personnel had reviewed the records and that product for the period from 10:30-12:30 had met requirements. Your records did not include documentation that you had taken corrective actions as specified in your HACCP plan to meet the requirements of 9 CFR 417.3(a), even though your records do not indicate that the product had met the critical limit.

Not meeting a critical limit indicates that the CCP is out of control, and therefore a potential for the development of a health hazard exists.

Verification 9 CFR 417.2(c)(7) and 417.4(a)(2):

9 CFR 417.2(c)(7) states that "*The HACCP plan shall at a minimum: List the verification procedures and the frequency with which those procedures will be performed, that the establishment will use in accordance with 417.4 of this part.*" According to 9 CFR 417.4(a)(2), "*Ongoing verification activities include, but are not limited to: (i) The calibration of process-monitoring instruments; (ii) Direct observation of monitoring activities and corrective actions; and (iii) The review of records generated and maintained in accordance with 417.5(a)(3) of this part.*"

3. Your HACCP plans for the pot pie line, dinner lines, and Dake line do not list record review at a specific frequency as an on-going verification procedure, as required by 9 CFR 417.4(a)(2)(iii).

4. Your HACCP plans for the fryer line and skillet meal/crock pot line includes a verification procedure for reviewing the calibration records at least once per week and you do have a pre-requisite program for calibrating your thermometers. However, this is not referenced in your HACCP plans for the fryer line or skillet meal/crock pot line and the HACCP plans do not include a procedures for calibrating your thermometers at a specific frequency as required by 9 CFR 417.4(a)(2)(i).

5. Your daily gravy system thermometer verification records indicate that on numerous dates, including 7/31/2007, 8/2/2007, 8/3/2007, 9/17/2007 and 9/20/2007, the difference between the verifying thermometer and the panel view temperature was greater than the five degrees specified in the procedures in your HACCP plan. However, your records do not indicate that these instruments were recalibrated to ensure their accuracy. Your establishment has not properly performed the procedures in your HACCP plan for the calibration of process monitoring instruments as required by 9 CFR 417.2(c)(7) in accordance with 9 CFR 417.4(a)(2)(i).

Since HACCP plans rely on accurate measurements when monitoring critical control points to ensure that critical limits are met, it is important to use properly calibrated process monitoring instruments. The goal of the calibration procedures is to ensure that all measurements are accurate. If the measurement of a particular parameter is not accurate, then the critical limit may not have been met. Not meeting a critical limit indicates that the CCP is out of control, and therefore a potential for the development of a health hazard exists.

On-going verification activities are key functions in the implementation of a HACCP plan to evaluate the day to day activities at a CCP to determine compliance with the specifics of the HACCP plan. Without adequate verification, FSIS cannot be sure that the food safety hazards are being controlled and safe products are being produced.

HACCP Records (9 CFR 417.5):

9 CFR 417.5(a)(2) states "*The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in 417.2 of this part, including all supporting documentation; (2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*"

6. You did not provide documents supporting the selection of your frequencies for the verification procedures in your HACCP plans as required by 9 CFR 417.5(a)(2).

According to 9 CFR 417.5(a)(3) "*The establishment shall maintain the following records documenting the establishment's HACCP plan: Records documenting the monitoring of CCP's and critical limits , including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot.*" In addition, 9 CFR 417.5(b) which states that "*Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*"

7. Your monitoring records include a space at the bottom of the form identified as "direct observation & verification". Establishment management explained that these are used to document your direct observation verification and the verification temperatures that are to be taken at the same time as specified in your HACCP plans for the pot pie line, dinner lines and Dake line. These records utilize the same date as the monitoring record and include the time, signature or initials and the verification temperature. However, these records do not include the results of the direct observation verification as required by 9 CFR 417.5(a)(3). These records also do not include the time recorded as required by 9 CFR 417.5(b).

8. Your record review verifications for CCP-1 for the pot pie line, dinner lines, Dake line and fryer line are recorded on a record review form that states that they have reviewed the records indicate that products for a specific time period have met requirements. These records also include the date and is signed or

initialed by the person making the entry. However, these records do not include the time recorded as required by 9 CFR 417.5(b).

9. Your record review verifications for CCP-2 for the pie line include a hand written entry in the upper margin of your monitoring records indicating that the record was "reviewed" and includes the date and is signed or initialed by the person making the entry. However, these records do not include the results of these record reviews as required by 9 CFR 417.5(a)(3).

10. Your thermometer verification records do not include the time recorded as required by 9 CFR 417.5(b).

Sanitation 9 CFR 416:

The Poultry Products Inspection Act, 21 U.S.C. § 456 and the Federal Meat Inspection Act, 21 U.S.C. § 608, gives the Secretary of Agriculture the authority to prescribe regulations (9 CFR 416) regarding sanitation in official establishments. 9 CFR 416.12 requires establishments to have written SSOP's that describe all the procedures they will conduct to prevent contamination of product. 9 CFR 416.13 requires them to perform all of these procedures as prescribed in the SSOP's. 9 CFR 416.14 requires an establishment to routinely evaluate their SSOP's and to revise them as necessary to keep them effective and current. 9 CFR 416.15 outlines the necessary corrective actions the establishment must take to ensure that sanitary conditions of product and product contact surfaces are adequately restored when a noncompliance is detected by either FSIS or establishment involving product or product contact surfaces. 9 CFR 416.16 outlines the record keeping requirements for both monitoring and implementation of corrective actions.

Sanitation Standard Operating Procedures (SSOP's):

According to 9 CFR 416.13(c), *"Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's. and 9 CFR 416.14 "Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operation, or personnel.*

1. The observations conducted by FSIS during the pre-operational plant inspections, and in correlating your program, which indicate that equipment will be disassembled and inspected. Therefore, in not breaking down these pipes other than at the connection sites for the pumps and holding tanks to perform an organoleptic technique of inspection, you have failed to demonstrate that effective evaluation of that cleaning procedure has been accomplished for these pipes used for edible product. This does not meet the requirements of their SSOP's according to 9 CFR 416.13(c). In addition, your environmental swabbing program that is used before and during operations to detect coliform and aerobic plate counts of the equipment is utilized to evaluate the effectiveness of your sanitation. You provided results as an example pertaining to the pie line for one day 5/02/2007 and a graph chart that reflects a period during 8/07/2006 to 9/27/2007 of the swabs collected. When questioning about what actions are taken when there is a spike in the graph, you indicated that if trends are evident then an evaluation of the area and/or corrective actions may be taken but no documentation of actions are recorded and that no base line or action limit is used. Therefore, by not effectively utilizing the results recorded or effectively monitoring procedures. You failed to demonstrate effective evaluation of their SSOP's according to 9 CFR 416.14.

Conclusion:

Meat and Poultry products are an important part of the nation's supply of food. They are consumed throughout the nation and the major portion thereof moves in interstate or foreign commerce. The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provides

that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. The Act gives FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products, or poultry products, to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that products are adulterated and provide definitions for the term "adulterated."

Title 21 U.S.C. 601(m)(4) of the FMIA states "The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances; (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" and 21 U.S.C. 453(g)(4) of the PPIA states "The term "adulterated" shall apply to any poultry product under one or more of the following circumstances; (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"

Under the authorities of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR 416 and 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (9 CFR 500). The Rules of Practice describe the types of enforcement action that FSIS may take and include procedures for taking a withholding action and or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of Federal inspection.

The assessment conducted at your establishment revealed that your establishment was not in compliance with the regulatory requirements for Sanitation Standard Operating Procedures (SSOPs) 9 CFR 416.13 and 416.14; and Hazard Analysis and Critical Control Points (HACCP) 9 CFR 417.2 and 417.5.

These findings demonstrate that your HACCP system is inadequate as prescribed in 9 CFR Part 417.6, which states that "*A HACCP system may be found to be inadequate if:*
(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by 417.3 of this part;
(d) HACCP records are not being maintained as required in 417.5 of this part"

These findings also demonstrate that your establishment's Sanitation Standard Operating Procedures have not been properly implemented or maintained.

FSIS has specified, through regulations 9 CFR 416 and 417, the conditions under which meat and poultry products must be produced. These regulations are essential, integral components of the regulatory system, and the failure, inability or unwillingness of an establishment to comply with these food safety regulations effectively precludes FSIS from making the determination that meat and poultry products are wholesome, not adulterated, and entitled to bear the marks of inspection.

Therefore, in accordance with FSIS Rules of Practice, 9 CFR 500.4(a) and (b) we are notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors at your facility.

Please be advised that, as a federally inspected establishment, you are expected to comply with the Federal Meat Inspection Act (FMIA) and all appropriate FSIS regulations. The regulations require establishments to take appropriate action when either establishment management or FSIS determines that the establishment's HACCP and/or SSOP system is inadequate. We are giving you the opportunity at this time to demonstrate: (a) why a

decision that your SSOP/HACCP systems are inadequate should not be made and (b) that you have achieved regulatory compliance.

Please provide this office a written response addressing each of those issues identified in the preceding pages within three (3) business days of the receipt of this letter. We will determine further actions, if any, based on your response.

Your response addressing the numbered issues above is expected to include the following three [3] things:

A.) A description of your findings concerning your HACCP system and SSOP's; a description of any planned or completed revisions made to your HACCP system and/or SSOPs, and improvements in the implementation of these programs. Your description is expected to include documentation of any new information and any changes already made, i.e., copies of new supporting documents and copies of any revised procedures.

B.) Details of your action plan, which must include all corrective/preventative measures you are taking or have taken. Again, if your action plan includes revisions to your HACCP procedures and/or SSOP's, please include documentation to demonstrate that those changes are being executed, i.e. HACCP, SSOP, or other applicable records, sufficient to demonstrate the proper execution of the new procedures.

C.) Please include a description of any other actions taken or to be taken, such as changes to the labeling of your product. For any action plan revisions or measures not yet completed, include the anticipated dates of completion and implementation.

If you have any questions regarding this matter, please contact me at the Lawrence District Office, 4920 Bob Billings Parkway, Lawrence Kansas 66049. The phone number at this office is 785-841-5600 and the fax number is 785-841-5623.

Sincerely,

Wm. M. Walker
District Manager

cc: A. Tawadrous, EARO
FO/QER
K. Goin, RM
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L. Johnson, DDM
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