United States Department of Agriculture

Food Safety and
Inspection Service

Office of Policy and
Program Development

Risk, Innovations, &
Management Staff
Patriot Plaza III

1400 Independence
Avenue, SW,
Washington, D.C.
20250-3700

May 30, 2017

Ms. Bridget Tinsley
Bridget C. Tinsley-Cormier
Senior Vice President, Technology & Business Development
PURE Bioscience, Inc.
1725 Gillespie Way
El Cajon, CA 92020

Dear Ms. Tinsley:

This letter is in response to your April 7, 2017, notification requesting to use a solution of silver dihydrogen citrate stabilized with sodium lauryl sulfate and citric acid (FCN 1768) in the spray or dip applied to poultry carcasses, parts and organs (Log Number 17-ING- 2110-N-A).

FCN 1768 is a solution of silver dihydrogen citrate stabilized with sodium lauryl sulfate and citric acid for use as an antimicrobial solution at levels up to 160 ppm silver dihydrogen citrate (silver) in the spray or dip applied to poultry carcasses, parts and organs. FCN 1768 is not for use in combination with any other silver containing antimicrobial and is not intended to be used in chiller baths.

The Food Safety and Inspection Service (FSIS) has completed its review of your request and has no objection to the use of FCN 1768.

Under the Federal Meat inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), FSIS is responsible for determining the efficacy and suitability of food ingredients in meat, poultry, and egg products. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads the consumer.

The use of this antimicrobial agent, as described in your notification, will need to be addressed in an establishment's hazard analysis and, as appropriate, incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan, Sanitation Standard Operating Procedures (SSOPs), or other prerequisite program, validated for its application, and verified on an "on-going" basis for its effectiveness. If the establishment does not address the effects of using FCN 1768 in its hazard analysis, FSIS would be unable to determine that product processed using FCN 1768 is not adulterated, and, therefore, the product would

not be eligible to bear the mark of inspection. This letter should not be considered as validation that your chemical or process would be effective in any particular official establishment.

Establishments are to provide appropriate engineering controls listed in the PURE CONTROL safety data sheet (SDS). Engineering controls include adequate general and local exhaust ventilation.

The use of FCN 1768 as an antimicrobial will become effective when it is listed in FSIS Directive 7120.1 "Safe and Suitable Ingredients in Meat, Poultry, and Egg Products."

As described in the FR Notice Vol. 70, No. 201, Pages 60784-60786, dated October 19, 2005, a summary description on your new ingredient will be posted on the Food Safety and Inspection Service New Technology Information Table. If you do not object within five business days from the date that you receive this letter, the Agency will post the included description of the technology on the Web site. If you do object to the description, you should state in writing that you object to the description, explain the basis for your objection (for example, proprietary agreement, confidential commercial information, etc.), and provide an alternate description. FSIS will post the alternate description, unless the Agency concludes that the description does not fairly describe the technology. In such a case, FSIS will post the description that it has prepared and will notify the company of its decision. FSIS will post the following summary of your new ingredient:

Log Number	Company Name	Summary of the Notification/Protocol
17-ING-2110-N-A	PURE Bioscience	A solution of silver dihydrogen citrate stabilized with sodium lauryl sulfate and citric acid in the spray or dip applied to poultry carcasses, parts and organs as an antimicrobial agent (FCN 1768)

This change will become effective when listed in FSIS Directive 7120.1 "Safe and Suitable Ingredients in Meat, Poultry, and Egg Products." The tables in FSIS Directive 7120.1 will be updated to include the following changes:

SUBSTANCE	PRODUCT	AMOUNT	REFERENCE	LABELING REQUIREMENTS

Antimicrobials				
An aqueous solution of silver dihydrogen citrate	As an antimicrobial solution applied by spray or dip on poultry carcasses, parts, and organs. Not for use in combination with any other silver containing antimicrobial and is not intended to be used in chiller baths.	For use at levels up to 160 ppm silver dihydrogen citrate in the spray or dip applied to poultry carcasses, parts, and organs.	Food Contact Substance Notification No. FCN 1768	None under the accepted conditions of use (6)
6) Food Contact Substance (FCS) subject to food contact notifications (FCN) is defined as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.				

Any future changes to this ingredient must be submitted to the Project Manager, Dr. John Hicks, with the Risk, Innovations, and Management Staff (RIMS) prior to implementation.

Any additional questions should be directed to Dr. John Hicks at (301) 504-0840 or via email at john.hicks@fsis.usda.gov.

Sincerely,

P.P.

Digitally signed by VALERIA GREEN
Date: 2017.05.30 15:48:51 -04'00'

William K. Shaw, Jr., PhD
Director
Risk, Innovations and Management Staff
Office of Policy and Program Development