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DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA/CFSAN/OFAS/DBGNR

**Memorandum**

Date: July 14, 2005

From: Timothy P. Twaroski, Ph.D.  
Food and Drug Administration, Center for Food Safety and Applied  
Nutrition, Office of Food Additive Safety, Division of Biotechnology and  
GRAS Notice Review.

Subject: FAP 9M4682

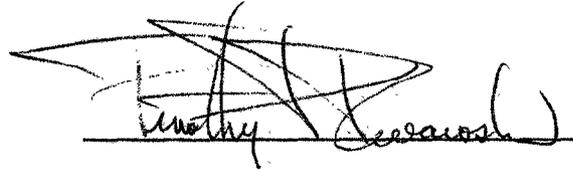
To: Lane Highbarger, Ph.D.  
Consumer Safety Officer, Division of Biotechnology and GRAS Notice  
Review

Toxicology Memorandum

Re: FAP 9M4682; Ionizing radiation for the control of *Vibrio* and other foodborne pathogens in fresh or frozen molluscan shellfish.

Toxicology was asked to address a comment submitted regarding data that implies that human consumption of irradiated potatoes has effects on systemic levels of hemoglobin. The data which appears to have been published by Maire Jaarma in 1967, shows that female hemoglobin levels fluctuate between 120 and 145 grams per liter, and male hemoglobin levels fluctuate between 140 and 175 grams per liter, during a fourteen week exposure to irradiated potatoes. The study does not present baseline levels of hemoglobin levels in either male or female subjects that will be exposed to irradiated potatoes. For comparison, the scientifically accepted range for hemoglobin in adult females is 120 to 160 grams per liter with 140 grams per liter being the average, and for adult males the range is 140 to 180 grams per liter with an average of 160 grams per liter (Guyton & Hall, Textbook of Medical Physiology, 9<sup>th</sup> ed., 1996). These data are also generally available on many websites such as Discovery Health (<http://health.discovery.com>) and Lab Tests Online (<http://www.labtestsonline.com>).

Based on the data submitted, which does not indicate a clear increase or decrease of hemoglobin levels in any human subject over the length of the study, and given the fact that none of the human subject hemoglobin levels ever appear to be outside the scientifically accepted normal range for hemoglobin levels, toxicology does not have any substantive information which would cause the agency to change its conclusion regarding the safety of irradiated products.

A handwritten signature in black ink, appearing to read "Timothy Twaroski", written over a horizontal line.

Timothy P. Twaroski, Ph. D.

cc: HFS-255 (RMartin, TTwaroski, LHighbarger)