DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

December 17, 2009

Dean Gambale
Tantaline
1050 Winter St., Suite 1000
Waltham, MA 02451

Dear Mr. Gambale

This is in reply to your inquiry concerning FDA's opinion of the suitability for food contact use of a tantalum surface applied to stainless steel (SS) by a chemical vapor deposition (CVD) process. You state that the composition of the tantalum raw material is 99.95% tantalum with trace levels of: O_2, C, Fe, N, Nb, H, Al, Ni, Mo, Cr, Ti, W, and Si.

You state and include documentation (Time of Flight Secondary Ion Mass Spectrometry, ToFSIMS, analysis) to support that the resulting tantalum surface on the SS substrate will be purer than the tantalum raw material. The documentation also indicates that there is a thin surface layer of TaO on the tantalum surfaced SS, and that there may be small amounts of Na, K, Ca and hydrocarbons (C_mH_n, e.g., C_2H_5, C_3H_7) that adsorb onto the Ta surface as transient surface contaminants. The tantalum surfaced SS articles are for repeated use in food processing equipment such as components of valves, fittings, and instrumentation that contacts food. The intended technical effect of the tantalum surface treatment is to confer additional corrosion resistance and chemical inertness to the stainless steel articles (exceeding the corrosion resistance and inertness of stainless steel 316).

If the tantalum surface remains chemically inert and resistant to corrosion and abrasion under their intended conditions of use, we believe that there is little or no likelihood that its components would migrate to food at other than insignificant amounts. FDA has historically issued favorable opinions on the use of such metals in contact with food, and we are currently not aware of any known or likely safety problem associated with the described intended use of the tantalum described. Therefore, we consider the tantalum acceptable for the intended use described and will not require premarket approval as a food additive under section 409 of the Federal Food, Drug and Cosmetic Act at this time (i.e., the submission of a food contact notification, a food additive petition or a threshold of regulation exemption request will not be required).

Please do not hesitate to contact us if you have any further questions.

Sincerely,

Vivian Gilliam for Kenneth McAdams

Kenneth McAdams
Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition