
From: Richard Stafford [<mailto:rstafford@protpot.com>]
Sent: Tuesday, May 29, 2012 12:42 PM
To: Saverot, Pierre
Cc: sales@jlshepherd.com; Stephen L. Hoffman; Kim Lee Sim; Peter Billingsley
Subject: JL Shepherd and Associates Special Permit SP 14766

Dear Mr. Saverot,

Sanaria Inc. uses a Model 484R-2 (serial number 7202) Co-60 irradiator containing 12,000Ci of Co-60 supplied by J.L. Shepherd and Associates. This irradiator is an essential component in the manufacture of Sanaria's novel malaria vaccine. Every year malaria is responsible for over 750,000 deaths, mostly of children in sub-Saharan Africa and some 300 million people become ill with malaria including 30,000 international travelers and military personnel. The research, development and current clinical testing of our vaccine is the culmination of over 9 years of investment by and close collaboration with the National Institutes of Health, National Institute of Standards and Technology, the Bill and Melinda Gates Foundation, and members of the European and African communities including the governments of Tanzania and the Netherlands, and the European Vaccine Initiative. This vaccine is currently in clinical trials at the NIH Vaccine Research Center and will soon be tested in a parallel trial in Tanzania.

The vaccine is composed of malaria parasites which are attenuated by irradiation using the 484R-2 irradiator. To meet our vaccine manufacturing requirements this irradiator requires reloading of Co-60 in the near future which is performed by JL Shepherd and Associates, the only entity licensed to perform the service. The possibility of not being able to reload the Co-60 in a timely manner and thus shutting down the entire vaccine development enterprise is unconscionable, as currently there is no effective malaria vaccine available which results in the death of over 7000 children daily as a result of malaria infection.

We hereby request that Special Permit SP 14766 possessed by JL Shepherd and Associates be extended until their new B(U) 650 package is approved and available, so that our irradiator may be reloaded on a timely schedule and our operations requiring use of the irradiator are not compromised. Since the quantity of Co-60 in our irradiator will require shipment of Co-60 sources in the near future using the GE 1500 container it would be helpful if the GE authorization for Limited Shipments using the 1500 package is extended.

Thank you for your consideration,

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