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April 14, 2000

Mr. Lou Carson
U.S. Food & Drug Administration
Center for Food Safety and Applied Nutrition
Deputy Director, Food Safety Initiative Staff (HFS-32)
200 C Street, SW
Washington, D.C. 20204

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Dear Mr. Carson,

I was president of Maine Biological Laboratories, Inc. (MBL) until my retirement in June of 1993. In 1990 I started working with Dr. H. Michael Opitz of the University of Maine and the State Veterinarian to control Salmonella enteritidis (SE) in a 12 house commercial egg complex in Maine. MBL produced an autogenous bacterin using SE isolates from that complex. Dr. Opitz set up a good program of clean out, disinfection, rodent control and the monitoring of houses. All replacement pullet flocks were injected two times with the autogenous SE bacterin before housing. After all laying houses had been turned around (over a years time) the whole complex was tested environmentally SE negative by Dr. Opitz. Over the next three years (especially the last year before my retirement), I spent much of my time working closely with large egg laying complexes in Indiana, Maryland, Connecticut and many in Pennsylvania. We used hundreds of millions of doses of SE Bacterin in hundreds of houses, in dozens of complexes, with excellent results. During that time, I spoke at several poultry health meetings presenting this data, and working directly with producers with SE problems.

I have now been retired for nearly seven years and have practically nothing to do with the poultry industry or the vaccine industry. However I did attend the New England Poultry Health Conference and listened to three presentations on S.E. including one by Dr. Marilyn Balmer. I also picked up a paper titled, Egg Safety: An Action Plan To Eliminate Salmonella Enteritidis Illness Due to Eggs. I was very concerned that neither the talk or the paper ever mentioned vaccine, bacterin or vaccination as part of a control program. I totally agree with the recommended program and the comments of Marilyn Balmer, regarding SE control in the poultry house, but it is missing the final necessary piece to make it successful - SE Bacterin or SE Vaccine (when approved). You are doing 95% of the job but without that final 5% you will make little or no progress. This has been shown over the last 10 years. Certainly the use of the SE Bacterin does not eliminate SE from the flock. However it does significantly reduce colonization of the gut that leads to ovary and oviduct infection necessary for passage in the egg. Certainly, SE Bacterin should only be used in complexes that have been proven environmentally SE positive.

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In the paper given by Dr. Amando Mirande at the New England Poultry Health Conference, he presented data from the Pennsylvania PEQAP program. His data showed that the non-vaccinated flocks on the PEQAP program had no significant improvement over 3 years. However flocks that followed the PEQAP program, but were also vaccinated, showed significantly less SE positive environmental samples (0.25% vs. 1.89%), significantly less SE environmentally positive flocks (2.9% vs. 10.6%) and **most important there were never any SE positive eggs in three years** compared to 7.4% - 10.8% and 5.7% in the non-vaccinated flocks on the PEQAP program but no vaccination. I hope that you will not ignore this kind of data which was produced on the Pennsylvania program even though it was presented by an employee of a vaccine company.

The New Hampshire meeting renewed my interest in SE. I have talked with Dr. H. Michael Opitz and Dr. Bob Eckroade and obtained a copy of your "Notice of Public Meetings" with a long list of questions. . After reading this, I decided that my experience might be of value, hence this letter.

Dr. Balmer stated that your goal is to reduce human SE by 50% in 4 years. I firmly believe that if you included vaccination with two shots of SE Bacterin in your program in SE contaminated egg laying complexes, that you could reduce it by 75% in 2 years after initiation of your program in these individual facilities.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth H. Eskelund DVM". The signature is written in black ink and is positioned above the printed name.

Kenneth H. Eskelund, DVM.

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