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December 20, 2004

United States Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504
RIN number 0910-AC14

To Whom It May Concern:

Please find enclosed comments on the above cited Docket and RIN number.
These comments have additionally been submitted by email and these are paper
documents to support the initial electronic comments.

We appreciate the FDA's consideration of all submitted comments on this matter from the
poultry and allied industries.

Sincerely,

A handwritten signature in black ink that reads 'Karen B. Grogan'. The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Karen B. Grogan

00N-0504

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**Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504
RIN Number 0910-AC14**

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The following comments address the above FDA docket number, titled – “Prevention of Salmonella enteritidis in shell eggs during production: Proposed Rule.

This program is an attempt by FDA to achieve the goals put forth by the Egg Safety Action Plan to eliminate SE illnesses associated with the consumption of eggs by 2010, with an interim goal of a 50 percent reduction in egg-associated SE illnesses by 2005. However, it falls short of reality, not even encompassing all available tools for Salmonella reduction. Salmonella spp. are ubiquitous organisms and challenges exist through many biological mechanisms in poultry house environments. All efforts laid out in the proposed rule, deny one important aspect of control that has been utilized by Egg Quality Assurance Programs (EQAP's) for years to reduce Salmonella enteritidis – vaccination. Aiding the bird's immune system in resisting infection is a very inexpensive tool that can greatly reduce the level of Salmonella in the poultry house environment.

Vaccination is completely disregarded in the proposed rule as an additional and efficacious aid in Salmonella control. An evaluation of two studies cited in the proposed rule background does not constitute a fair evaluation of the usefulness of vaccines. The 99 NAHRMS layer study was a survey of only 200 layer houses in the US poultry industry. Their results of only 7% vaccinated flocks cannot be considered an accurate evaluation of market use. That data point is a result from the written survey part of the study, which reported a low response rate.

The actual use of biologics on layer farms to aid in control of Salmonella is much higher than the data represented in that study. In public information from CVB, all biologics companies in 2002 sold a combined total of 75 million doses of inactivated Salmonella bacterins. According to a biologics survey (Merial Vaccine Survey) of layers in 2001, out of 111 million birds in the survey, 2% of respondents indicated they used live Salmonella vaccines and another 2% inactivated Salmonella bacterins – 4.4 million birds between the two types of vaccines.

All Salmonella live vaccines and bacterins have been proven efficacious by Center for Veterinary Biologics as “an aid in the reduction of Salmonella enteritidis colonization of the internal organs.” If they did not meet these label claims through stringent research, CVB would not approve their label claims. All label claims have to be supported by efficacy data showing a statistically significant difference in those subjects receiving the vaccine and non-vaccinated controls. An attached Word file will show efficacy studies for a licensed Salmonella bacterin.

In order to limit the data in this comment document, a separate attached Adobe file shows the effect one licensed live vaccine, Megan[®] Egg, has on reduction of Salmonella enteritidis in layer type birds. This vaccine is the only one approved with a label claim for use in older, layer chickens. The birds were vaccinated with three doses, per label indications, at 2, 4, and 16

weeks of age. Reduction of the challenge strain was proven in all examined organs, and data showed significant reduction into the egg. This data was provided to USDA, however a label claim was not allowed since the egg itself falls under FDA jurisdiction. For that reason, the label indications show protection of the ovaries and oviduct – the important reproductive organs.

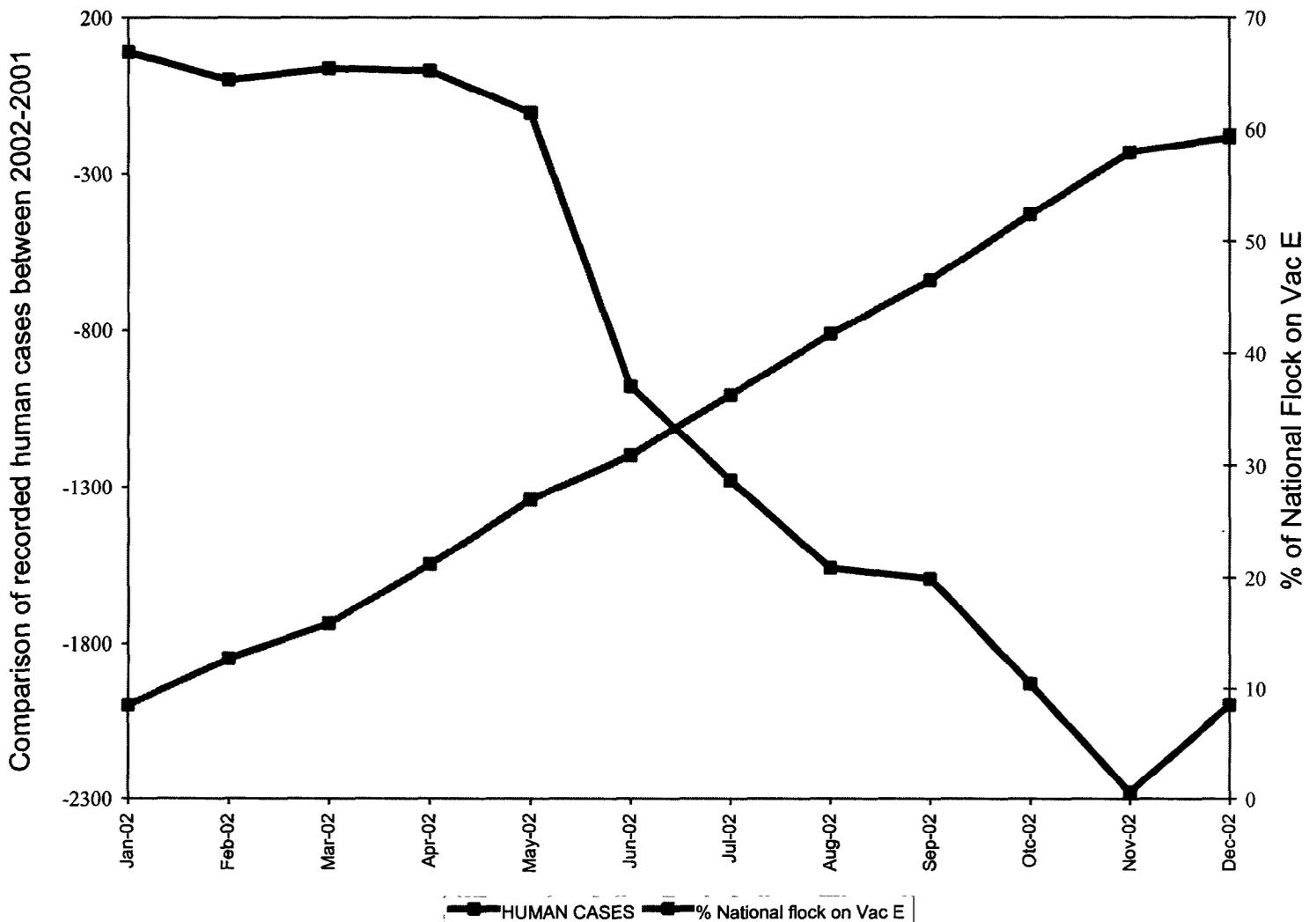
The FDA should reference other nation’s control plans – many reference mandatory vaccination as an integral part of their programs. The United Kingdom has experienced high levels of human disease from SE since the mid 90’s. Their egg industry instituted a SE control program, with one of the key aspects being mandatory use of vaccines in chickens for SE. According to a report from 2001, their Food Standards Agency, Advisory Committee on the Microbiological Safety of Food – they cite “There has been a sustained drop in human Salmonella cases since 1997. We believe that this reflects a corresponding fall in the levels of Salmonella in eggs. There are reasons for believing that these improvements flow from the widespread vaccination of egg laying flocks against Salmonella enteritidis, combined with improved flock hygiene measures.”

This report can be found at the following link:

<http://www.food.gov.uk/multimedia/pdfs/ACAF00126.pdf>

One of the vaccines approved in the UK market is TAD Salmonella Vac E – an attenuated and marked strain of Salmonella enteritidis that is highly safe and efficacious. This product is administered via drinking water, however it is not available here in the U.S.

The following graph shows the increase in sales of this vaccine and resulting decline in human cases of salmonellosis:



Additionally, the UK Food Standards Agency recently completed a survey of retail eggs, which was reported March 2004. Their results show a “three-fold reduction in the level of salmonella contamination since their last survey in 1995-1996 and this is likely to reflect the measures introduced by the UK Egg Industry to control salmonella.”

This report can be found at the following link:

<http://www.food.gov.uk/multimedia/pdfs/fsis5004report.pdf>

Conclusions:

Other comments on this proposed rule offer additional important information in regards to testing, financing, biosecurity, egg handling, please reference USAHA comments for expanded information on those subject areas and additional references on vaccination.

As concerned poultry veterinarians, we all would like to see a reduction in Salmonella enteritidis. However, this plan is not ideal in its current form and would financially strain producers, state labs and the federal government.

Voluntary programs already in existence have already significantly reduced SE in major egg producing areas. Why reinvent the wheel and force producers to change their existing SE control programs to suit FDA legislation? Many producers have already achieved SE negative status, with some of the lapses in this proposed rule, they could potentially turn positive.

Please consider all submitted comments from our industry. Integration of the comments from national and world experts will greatly improve the success of this proposed rule.