August 5, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE 99-19

Subject: Autogenous Virus Vaccines for Infectious Salmon Anemia Virus

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team
Area Veterinarians in Charge, VS
State Veterinarians

The purpose of this notice is to inform interested parties that, in the event of an outbreak of Infectious Salmon Anemia Virus in the United States, the Animal and Plant Health Inspection Service (APHIS) will allow the preparation of Autogenous Infectious Salmon Anemia Virus Vaccines for use in commercial United States salmon production facilities. This is in accordance with the provisions of 9 CFR 113.113(a)(3). Distribution in each State shall be limited to authorized recipients designated by the Administrator of APHIS and the proper State officials, under such additional conditions as these authorities may require.

Infectious Salmon Anemia (ISA), which is caused by an Orthomyxovirus, has produced disease and mortality in Atlantic salmon in Norway (first disease outbreak in 1984), Canada (1996), and Scotland (1998). Mortality is variable; mean mortality has been 12 percent over a 60-day period, but has been as high as percent per day in some cases. Transmission occurs from fish to fish by contact with infected fish, with parts from infected fish (including mucus, blood, feces, viscera, trimmings, muscle), or with equipment contaminated with parts from infected fish. Farms within a distance of 5 kilometers (3.1 miles) from infected farms are reported to be at a 5-to-13 times higher risk of infection.

ISA disease control programs have varied. Norway has emphasized the development of "ISA-free zones", and established controls on the location of production and processing facilities, and restrictions on the movement of fish and equipment from infected areas to ISA-free zones. Scotland adopted a compulsory slaughter regime for infected facilities, and established zones surrounding infected farms within which all farms must fallow (not stock) their pens for 6 months. In Canada certain ISA-infected areas were fallowed and repopulated; however, this regime was felt to be inappropriate for the New Brunswick region, since many pens are geographically close to one another. Canadian aquaculturists in New Brunswick began vaccinating smolts with an autogenous vaccine in the winter of 1998, and have chosen to vaccinate the fish in their 1999 year class smolts.

Although ISA virus has spread no more than 15 miles from its initial site of infection in New Brunswick, the entire salmon farming industry in the Bay of Fundy area (including Maine), exists within a 25-mile radius of this focus of infection. With Maine salmon pen sites within a 3-mile radius of recently infected Canadian sites, Dr. Alfonso Torres, Deputy Administrator, Veterinary Services, established a Working Group to develop program recommendations regarding ISA, and to develop and coordinate ISA diagnostic and control activities. On July 7, 1999, Dr. Torres signed a Memorandum allowing the production and use of ISA virus vaccines in the United States with the provision that distribution in each State shall be limited to authorized recipients designated by the Deputy Administrator of APHIS Veterinary Services and the proper State officials — under such additional conditions as these authorities may require.

The regulations in 9 CFR 113.113 state that autogenous biologics shall be prepared from cultures of microorganisms which have been inactivated and are nontoxic. Such products must be prepared only for use by or under the direction of a veterinarian under a veterinarian-client-patient relationship, except that such products may be prepared for use under the direction of a person of appropriate expertise in specialized situations such as aquaculture, if approved by the Administrator. Autogenous biologics must be produced using seed organisms isolated from sick or dead animals in the herd of origin; however, the Administrator of APHIS may authorize preparation of an autogenous biologic for use in herds adjacent to the herd of origin or in herds which are not adjacent to the herd of origin. The appearance (isolation) of ISA virus in U.S. waters would be considered adequate justification for authorizing the use of this vaccine in adjacent and non-adjacent commercial U.S. salmon production facilities.

Prior to initiating work with the ISA virus, an applicant should designate the facilities to be used and specify the precautions which will be taken to prevent contamination of licensed products and should submit this information to the Center for Veterinary Biologics. In addition to applications for autogenous vaccines, we will also consider applications for Veterinary Biological Product Licenses (9 CFR 102.5) and Conditional Veterinary Biological Product Licenses (9 CFR 102.6) for Infectious Salmon Anemia Virus Vaccines.

/s/Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics