Federal Service for Supervision of Consumer Rights Protection and Human Welfare

Federal State Scientific Establishment

STATE RESEARCH CENTRE FOR APPLIED MICROBIOLOGY AND BIOTECHNOLOGY (FSSE SRC AMB)

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CONCLUSION

in evaluation of pathogenicity in a strain

FSSE SRC AMB conducted the evaluation of **pathogenicity in** *Bacillus F* **strain** submitted by Tyumen Scientific Centre of Siberian branch of Russian Academy of Science.

The assessment of pathogenicity in the above strain has been performed by conducting an experiment of infecting Swiss Webster outbred mice (weight 20-24g, age 10-12 weeks) with a one-day culture in a dose of 10^6 , 10^7 and 10^9 per animal by four methods: *per os* (forced watering through tube), intravenously, intraperitonially and subcutaneously. The number of animals in each group -10. Observation period after the infecting -21 day. The control groups of animals were treated by normal saline and the culture of pathogenic strain *Bacillus cereus* according to the same regime. During the assessment of the pathogenicity of the investigational strain, the data of the bacteria inoculation rate from blood and spleen, as well as the survival rate and weight of animals has been taken into account. The experiments have been conducted in accordance with the Guide for Care and Use of Laboratory Animals (1996).

Animals have been euthanized by using carbon dioxide.

It has been observed in the result of the tests:

- 1. No deaths among the test animals infected with the bacteria of the investigational strain during the observation period (21 days);
- 2. No swelling or hyperemia in the places of bacterium input in the test animals 24 hours after treatment;
- 3. No bacteria inoculation from the organs of the animals infected with the investigational strain culture and euthanized after the expiry of 21-day observation period.

Basing on the results obtained the conclusion on non-pathogenicity and avirulence of the strain $Bacillus\ F$ has been made.

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/Seal: Federal Service for Supervision of Consumer Rights Protection and Human Welfare, Federal State Scientific Establishment, State Research Centre for Applied Microbiology and Biotechnology (FSSE SRC AMB)/