GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE OF DRUG ADMINISTRATION
105-106, Motijheel Commercial Area, Dhaka.

CERTIFICATE OF REGISTRATION

We hereby declare that **OKAVAX** manufactured by **The Research Foundation for Microbial Diseases of Osaka University (BIKEN), 3-1 Yamada-oka, Suita, Osaka, Japan** and represented by **M/s. Sanofi-aventis Bangladesh Limited, 6/2/A Segun Bagicha, Dhaka-1000, Bangladesh** is registered with Directorate of Drug Administration and Licensing Authority (Drug) under Registration No. 102-4414-09. The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act. 1940 (XXIII of 1940)** and Drug (control) Ordinance 1982 subject to the provision of import policy published by Government from time to time.

Name of the Product	:	**OKAVAX.**
Dosage Form	:	**Solution for Injection.**
Pack Size	:	**1 vial contains one dose. Solvent (water for injection J.P): 0.7ml per vial is provided.**

Composition: 0.7ml contains the following:

Ingredient(s)	Specification	Quantity
A. The Vaccine (1 vial) contains:		
An attenuated live Varicella-zoster Virus (OKA Strain)	JP	≥ 1400 PFU
Sodium Chloride	JP	1.6 mg
Potassium Chloride	JP	0.04 mg
Monobasic Potassium Phosphate	JIS	0.4 mg
Dibasic sodium phosphate hydrate	JP	4.395 mg
Sucrose	JP	35.0 mg
Monosodium L-glutamate monohydrate	JPC	0.5 mg
Kanamycin Sulfate	JP	≤ 10µg (potency)
Erythromycin Lactobionate	JP	≤ 3µg (potency)
B. The diluent (1 vial) contains		
Water for Injection	JP	0.7 ml

Instructions
To be dispensed only by or on the prescription of a registered physician.

21 JUN 2009

Brigadier General Ismail Hossain
Director
Directorate of Drug Administration
and
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

Conditions

(1) Labeling should contain name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) DAR No. (Drug Administration Registration Number) etc. should be displayed on the label or container and also on the outer cover containing the container.
(2) The registration will be valid for 05(five) years from the date of issue unless it is revoked, suspended or cancelled earlier.
(3) The certificate will be treated as cancelled if any violation of conditions and the name or the formula of this product changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No.DA/..15-5(102)97/5469
Date 22/06/09

C.C. M/S. Sanofi-aventis Bangladesh Limited
6/2/A, Segun Bagicha, Dhaka-1000,
Bangladesh.

For Director
Directorate of Drugs Administration
22/06/09