GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE

DRUGS ADMINISTRATION
105/106, MOTIJHEEL COMMERCIAL AREA, DHAKA-1000

CERTIFICATION OF REGISTRATION
(FOR THE IMPORT OF NEW AND UNINTRODUCED DRUGS AND MEDICINE)

We hereby declare that Act-HIB manufactured by ~~PASTEUR MERIEUX CONNAUGHT~~ Sanofi Pasteur SA, 58, Avenue Leclerc-69007 Lyon, FRANCE and represented by ~~Rhône-Poulenc Rorer~~ Sanofi-aventis Bangladesh Ltd. registered with the Directorate of Drugs Administration under the Ministry of Health & Family Welfare under Registration No. 102-3173-97..... The drug as described below is allowed to be imported into Bangladesh under Drugs Act 1940 (XXIII of 1940) and Drug (Control) Ordinance 1982 subject to the provision of import policy published by the government from time to time.

Name of Preparation : **Act-HIB**
Form : Injectable preparation
Packing : 1 Vial 1 Dose + 1 Syringe Diluent, 1 Box x 10 Vials, 1 Box x 10 ampoule
Sub cutaneous or intramuscular route
Composition : For one vaccinating dose :

29.10.97

a. INGREDIENT	SPECIFICATION	QUANTITY
Haemophilus influenzae type b Polysaccharide conjugate to tetanus protein	INN	10 µg
b. EXCIPIENTS :		
Tris (hydroxymethyl aminomethane)	Company monograph	0.6 mg
Sucrose	Eur. Ph.	42.5 mg
Sodium chloride	Eur. Ph.	2.0 mg
c. DILUENT :		
Water for injections	Eur. Ph.	up to 0.5 ml

This Certificate shall remain valid for five years from its date of issue unless it is revoked, suspended or cancelled earlier.

M. A. Malek 29.10.97

Muhammad Abdul Malek
Director (in charge)
Directorate of Drugs Administration
&
Licensing Authority (Drugs)

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

Conditions: (1) Labelling should contain name and address of the manufacturer, batch number, manufacturing date, expiry date, M.R.P. (maximum retail price), DAR No. (Drug Administration Registration Number), (where applicable) 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 5 (five) years unless it will be canceled earlier. (3) The certificate will be treated as canceled in any violation of the conditions and the name of the formula of this product changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA/15-5/102/97/5140 Date...10.11.97...

c.c. to 1. ~~Rhone Poulenc Rorer~~ Sanofi-aventis Bangladesh Ltd. Station Tongi, Gazipur Khan 29.10.97
For Licensing Authority (Drugs)
Drugs Administration.

CC, 612/A, Segun Bagicha. Dhaka.

This Registration shall remain valid
upto 28-10-2017 unless it is suspended
Cancelled or revoked earlier.

সহকারী পরিচালক ০৪/১০/১২
ঔষধ প্রশাসন পরিদপ্তর
এবং
লাইসেন্সিং কর্তৃপক্ষ (ড্রাগস)
গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

This Registration shall remain valid
upto 28-10-2017 unless it is suspended
Cancelled or revoked earlier.

সহকারী পরিচালক ০৪/১০/২০১২
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This Registration shall remain valid
up to 28-10-2017 unless it is suspended
Cancelled or revoked earlier.

M Salahuddin 10.06.13
Md. Salahuddin
Assistant Director
For Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh