European Directorate for the Quality of Medicines
Certification Unit

Certificate of suitability
No. R1-CEP 2000-112-Rev 00

1 *Name of the substance:*
2 **FOETAL BOVINE SERUM**

3 *Name of holder:*
4 **BIOLOGICAL INDUSTRIES ISRAEL BEIT HAEMEK LTD**
5 IL - 25115 Kibbutz Beit Haemek

6 *Site of production:*
7 **BIOLOGICAL INDUSTRIES ISRAEL BEIT HAEMEK LTD**
8 IL - 25115 Kibbutz Beit Haemek

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
10 **R0-CEP 2000-112-REV 02**

11 After examination of the information provided on the origin of raw material(s) and type of
12 tissue(s) used and on the manufacturing process for this substance on the site of production
13 mentioned above, IL - 25115 Kibbutz Beit Haemek, we certify that the substance **FOETAL**
14 **BOVINE SERUM** meets the criteria described in the current version of the monograph Products
15 with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European
16 Pharmacopoeia, current edition including supplements.

17 - countries of origin of source materials: Australia and Panama
18 - nature of animal tissues used in manufacture: Fœtal bovine blood

19 The submitted dossier must be updated after any significant change that may alter the quality,
20 safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform
21 encephalopathy agents.

22 Manufacture of the substance shall take place in accordance with a suitable quality assurance
23 system such as ISO 9001, and in accordance with the dossier submitted.

24 Failure to comply with these provisions will render this certificate void.

25 The certificate is valid provided that there has been no deterioration in the TSE status of the
26 country(ies) of origin of the source material.

Postal Address: 226 Avenue de Colmar (entrance rue Schertz) B.P. 907 — F 67029 Strasbourg Cedex 1
Telephone: 03.88.41.30 30 - Fax 03.88.41.27.71 - E-mail: certification@pheur.org

This certificate is renewed from **19 February 2006** according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has 30 lines only.

Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 3 February 2006

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

BIOLOGICAL INDUSTRIES ISRAEL BEIT HAEMEK LTD, as holder of the certificate of suitability

R1-CEP 2000-112-Rev 00 for FOETAL BOVINE SERUM

hereby authorises .....
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

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