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June 30, 2009

Committee For Human Medicinal Products (CHMP)  
European Medicines Agency (EMA)  
7 Westferry Circus  
Canary Wharf  
London, E14 4HB

**Re: Docket Ref. EMA/410/01-Rev. 4**

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the European Medicines Agency (EMA) for the opportunity to submit comments on the *Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents Via Human and Veterinary Medicinal Products – Revision 4*.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO welcomes the revision of this note for guidance in line with industry and agency experience gained since the issuance of the previous note for guidance on *Transmissible Spongiform Encephalopathy*. In general, the revisions are welcome. However, BIO members have concerns regarding the alignment of Revision 4 with other requirements. In particular, BIO seeks clarification that European Directorate for the Quality of Medicines & Health Care (EDQM) issued certificates of suitability for suppliers will remain valid until their current expiry date. Such certificates are currently awarded a five year expiry period under Resolution AP-CSP

(07)1. If the certificates do not remain valid, product withdrawal may occur and may interrupt product availability to patients.

The revisions require manufacturers to confirm with their suppliers that the new conditions are being met in regard to the new criteria recommended for the sourcing and/or processing of gelatin, bovine blood derivatives, collagen, peptones and re-classification of risk for materials used in the manufacture of medicinal products for human or veterinary use. This confirmation process will take time to be accomplished.

BIO recommends that the EDQM TSE Certificates of Suitability remain in effect until the next required re-evaluation (i.e. expiry date), and that suppliers be required come into compliance with the Note for Guidance Rev. 4 at that time. In turn, we suggest that the marketing authorization holders referencing the certificates be required to submit a variation within 90 days of the re-issued EDQM TSE Certificates of Suitability.

Thank you again for the opportunity to comment. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Sara Radcliffe  
Vice President, Science & Regulatory Affairs  
Biotechnology Industry Organization (BIO)