

### **FDA acceptance ó general condition**

With regard to the fact that CR is a member country of OECD, this monitoring organ for the area of pharmaceuticals is the State Institute for Drug Control (SÚKL). The legal status in this area follows the public notice of Ministry of Health and Ministry of Agriculture No. 504/2000 Czech Collect. of Law, whose integral part is an accurate translation of the document "Decision of OECD Committee C(97)186(final)", i.e. the "Principles of Good Laboratory Practice (GLP) OECD", which are binding on all member states of OECD inclusive of the USA.

Hence the National Program of Good Laboratory Practice is valid in the CR like in other member countries of OECD, and this Program *inter alia* specifies the procedures of monitoring of compliance with GLP, checking of test facilities, and audits of studies. BioTest possesses the GLP Certificate (the last inspection was carried out in October 22 ó 24, 2007 and the next shall take place in October 2009) and is subject to regular inspections from the side of SÚKL, the results of inspections being available on the Internet pages of SÚKL and OECD.

If the national monitoring organ confirms the compliance with GLP, i.e. confirms that the given testing facilities work in accordance with GLP Principles and grants the corresponding Certificate, then this document is valid in all member countries of OECD inclusive of the USA. Hence there is no legal barrier for FDA to accept such a study.

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A handwritten signature in blue ink, appearing to read "Ivana Surova", is positioned to the right of the typed name and title.