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MARKETING AUTHORIZATION PROCEDURE FOR VETERINARY IN VITRO DIAGNOSTICS IN GERMANY

J. Heidrich, J. P. Teifke

In vitro diagnostics, which have been produced either biotechnologically or by use of pathogens and which are destined for the prevention, diagnosis or treatment of animal diseases, generally may only be placed on the market or administered after an official marketing authorization has been granted. In Germany, the competent authority for granting marketing authorizations (licensing authority) for products that are not destined for the application in animals is the Friedrich-Loeffler-Institut (FLI), Federal Research Institute for Animal Health. The procedure is initiated after submission of an application by the pharmaceutical entrepreneur. This is the person who places the product on the market under his own name (manufacturer, distributor). To this end, he must have his registered place of business in a member state of the EU or in a contracting state of the Agreement on the European Economic Area. The experimental testing required for a decision on the marketing authorization will be done in the respective test laboratory of the FLI, which is in most cases a reference laboratory for the disease in question. After the marketing authorization has been granted, each batch of a product must be tested and can only be marketed or applied after release by the competent licensing authority. In 2012, the FLI granted 23 marketing authorizations and carried out more than 244 batch releases and 439 batch registrations (after exemption from batch testing). This underlines the high quality standard of in vitro diagnostics applied in Germany.

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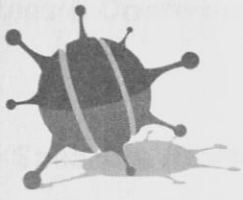
Deutsche Veterinärmedizinische Gesellschaft e.V.
German Veterinary Medical Society

16th International Symposium of the World Association of Veterinary Laboratory Diagnosticians (WAVLD)



10th OIE Seminar

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June 5 – 8, 2013
Berlin, Germany

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