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The delay in the examination of applications for registration at ANVISA and lawsuits in Brazil

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According to Law 6.360/76, ANVISA has 90 days to approve or reject the application for registration of the products that are submitted to it. However, the reality is quite different in Brazil. Applications for registration must be submitted with several documents, including the certificate of good manufacturing practices (or an equivalent that is recognized by ANVISA). Therefore, the companies have to apply for a factory inspection in national or international territories, prior to applying for registration. This inspection is taking too long to take place and companies are seeking assistance from the courts to determine that ANVISA inspect on tighter deadlines. As noted, the delay for a product to be registered with ANVISA starts even before making such a request. After the factory inspection is performed, the next step is to request registration with ANVISA. Law 6.360/76, specifically in Article 12 (§ 3), which defines that ANVISA should obey the period of 90 days from the registration request protocol. However, the law is not enforced by ANVISA. And again, many companies request to the courts that ANVISA obey the deadline. Importantly in some cases there is no guarantee that the approval will be granted by ANVISA, because everything will depend on the documentation that the company submits with their request, information about the product, among other necessary information. Brazil is not always driven by lawsuits so that their applications are reviewed. There are companies that prefer not to go to court; they rather solve their issues directly with ANVISA, through meetings or applications that warrant priority in the analysis. ANVISA is seeking to speed up the analysis of these orders, and no effort to better serve the companies and especially the population.

Biography

Marcio Raposo de Almeida has completed his specialization in public health surveillance and health by the Office of Science, Technology and Industrial Quality - ICTQ and his law degree from Universidade Candido Mendes. He is the director of MRA Consulting Business having acquired extensive experience in the regulatory and legal area, especially when it comes to ANVISA.

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