

FDA Office of Generic Drugs Question-Based Review Initiative: An Update—Past, Present, and Next Steps

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The Question-Based Review (QbR) initiative of the Office of Generic Drugs (OGD) has reached its second full year in 2009. From a human perspective, we can say that QbR has reached “toddlerhood.” And like a true toddler, QbR has come out of its infancy, exploring new ground, trying to define and redefine itself. As abbreviated new drug applications (ANDA) submitted in the QbR format have become the industry norm and the “growing pains” with the new submission style are waning to some degree, it is an appropriate time to provide the industry with some perspective regarding...

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