

DESI Documents in PharmaPendium

What are (Drug Efficacy Study Implementation) DESI documents?

Drugs which the FDA approved prior to 1962 were not required to prove efficacy, only safety. Following the Kefauver-Harris Drug Control Act that was implemented in the 1960s, drugs which were on the market needed to be classified as either effective, ineffective, or needing further study. The FDA contracted this work to the National Academy of Science/National Research Council (NAS/NRC), and the reports were submitted to the FDA in the late 1960s and early 1970s. The DESI documents provide information on the studies which were conducted and the conclusions which arose from those studies.

Why are DESI documents important?

Drugs that have been given a “DESI” status are drugs which were approved by the FDA prior to 1962, but may not have necessarily passed the efficacy evaluation in the DESI reports post 1962. These drugs may still be on the market and presents an interesting opportunity for sponsors to develop similar compounds (or in some cases the same “DESI” compound) and get them approved by the FDA for the same indication. Once an approved product is marketed, the FDA is expected to enforce the removal of the unapproved “DESI” products, in effect creating market exclusivity for the newly approved product.

Opportunity to use the 505(b)(2) regulatory pathway for faster drug approval

Since the “DESI” drugs have been on the market for a long period of time, chances are these drugs have been already used for one or several indications, with an acceptable drug safety risk profile. Sponsors can use the information found in the DESI documents to understand what additional studies may be needed to gain approval, and may be able to complete the 505(b)(2) with just the supplemental safety and efficacy studies, which requires less time and resources

How can I find DESI documents in PharmaPendium?

These documents have been made text searchable in PharmaPendium. If an approved drug has an associated DESI document, you can find a link to this document on the drug information page, or you can perform a text search on DESI documents specifically. Simply restrict your Quick or Advanced search to DESI documents in the Sources filter.