**DESI: Drug Efficacy Study Implementation**

Drugs that had been marketed prior to passage of the Food, Drug, and Cosmetics Act in 1938, were permitted to remain on the market. Ultimately, some were submitted for approval in NDAs in their existing or in new formulations. Others were shown to be ineffective or dangerous and were abandoned. In 1968, FDA established “Drug Efficacy Study Implementation” or DESI with the aim of evaluating drugs that had not yet undergone clinical trials and review. About 160 drugs have still not been reviewed yet are available on the market. Known as DESI drugs, many are still used in dermatology—coal tar, sulfur, sodium sulfacetamide, and hydroquinone, among them.

Due to limited FDA resources, review of drugs is not a priority, and the agency occasionally scrutinizes agents in response to emerging safety concerns or other developments. In most cases, FDA essentially charges industry with the responsibility to design, conduct, and report clinical trials to demonstrate safety and efficacy.

Hydroquinone 2% as an OTC product is DESI and has gained significant attention lately. The Agency had asked manufacturers to submit data on hydroquinone, but the deadline has passed, and next steps remain to be seen. Costs to design and conduct large-scale trials for these hydroquinone products likely would not be justified by the profits manufacturers make from them. In light of the industry’s lack of response, FDA could ban hydroquinone 2% from the OTC market.