the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples.

c. FDA Recommends Changing the Brand Name

A practical application of DMEPAs's tasks is shown as part of FDA's evaluation of NDA 050810, available on Apr. 2007 on the FDA's website. DMEPA had made a recommendation for a name change, but the FDA reviewer refused to accept this recommendation. The brand name of the study drug was AzaSite® and the brand name of the other drug was AquaSite®. The FDA reviewer stated that, "DMETS does not recommend the use of the name AzaSite … the primary concerns were relating to look-alike confusion with … AquaSite." However, the FDA reviewer disagreed with DMETS, stating that, "AquaSite is not … a concern because the product … was removed from the market and has not been marketed in several years."

Please note that DMPEA was formerly named, Division of Medication Errors and Technical Support (DMETS).

d. FDA Recommended Changing the Chemical Name

Another practical application of DMEPA's tasks is shown as part of FDA's evaluation of NDA 022250, located on Jan. 2010 of FDA's website. The *Summary Review* stated that:

> [l]ate in the review process, it became clear that the established chemical name "fampridine" was very similar (especially in appearance when hand written) to the established name for "famotidine", and that therefore there was a risk for medication errors involving these two drugs. Although famotidine is an over-the-counter (OTC) drug at low doses, higher doses that overlap with the fampridine dose are available by prescription. For this reason, we asked the sponsor to propose another established name. They have done so, proposing "dalfampridine", which we find acceptable.

e. FDA's Decision-Making Process in Recommending a Prefix Be Added to a Name

This is from FDA's *Proprietary Name Review*, for *trastuzumab emtansine*. The information is for BLA 125418, on Aug. 2012 of the FDA's website.

This review concerned confusion of the chemical name (trastuzumab emtansine) with the chemical name of another drug, *trastuzumab*. The issue was that, even though the brand names for the two drugs were extremely different from each other (Kadcyla® vs Herceptin®), the chemical names were very similar.

In a nutshell, FDA recommended that the Sponsor modify the chemical name of the drug to include a prefix. As is evident from the package label, the Sponsor complied with the FDA's request, and changed the chemical name to include a prefix. The new name was, "*ado-trastuzumab emtansine*."

The similarities were not just in the chemical names, but also in the type of clinic and patient population. The FDA reviewer outlined a general problem, occurring when physicians fill out prescriptions, writing that:

> Due to the fact that healthcare providers may use nonproprietary names instead of proprietary names when prescribing and ordering products, and confusion has already occurred in clinical trials, FDA has determined the use of **distinct proprietary names is insufficient** to adequately address the Agency's safety concerns with use of "trastuzumab emtansine" as the proper name for Kadcyla.

The FDA reviewer complained that the chemical name, "trastuzumab emtansine," is