A question that might arise is, "Why not just print the name of the active ingredient on the package label?" Anton et al. (73) provides the answer that, "[t]he use of brand names serves to distinguish products with the same active ingredient but different formulation or indication."

Medication errors can arise because of confusion caused by the brand name, or from the packaging. FDA recognizes that, "medication errors are a significant public health concern that accounts for an estimated 7000 deaths annually in the United States" (74). Confusion can arise during prescribing, administration, and monitoring recovery of a patient. According to FDA's Guidance for Industry, "FDA considers the potential for confusion throughout the entire U.S. medication-use system, including product procurement, prescribing and ordering, dispensing, administration, and monitoring the effects of the medication" (75).

Gershman and Fass (76) point out that consumers and healthcare professionals can report medication errors through a program administered by the Institute for Safe Medication Practices (ISMP), that individuals can describe the medication error, and the drug, and this is followed by ISMP distributing alerts.

The documents medication errors resulting from inconsistent units. The inconsistent units were milligrams and teaspoonfuls, in a container of oseltamivir (Tamiflu®) for children. Parker et al. (77) revealed that the problem was that, "[t]he medication bottle was accompanied by a prepackaged syringe with markings of 30, 45, and 60 mg … [t]he label attached by the pharmacy specified the dose in volume units (3/4 teaspoonful) but the syringe provided only markings in mass units (milligrams). Despite these disparate directions, the parents were eventually able to determine the correct dose."

b. Division of Medication Error Prevention and Analysis

An office in the FDA, *Division of Medication Error Prevention and Analysis* (DMEPA), reviews the proposed names of drugs, and evaluates the brand name as well as the chemical name. Comments in the *Medical Review* for BLA 125418, on Aug. 2012 of FDA's website, provides a general account of the tasks performed by DMEPA. The reviewer wrote:

> The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because

[73]Anton C, et al. Using trade names: sometimes it helps. Arch. Intern. Med. 2002;162:2630.

[74]U.S. Department of Health and Human Services. Food and Drug Administration. Best practices in developing proprietary names for drugs; May 2014 (33 pp.).

[75]U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for industry. Contents of a complete submission for the evaluation of proprietary names; February 2010 (19 pp.).

[76]Gershman JA, Fass AD. Medication safety and pharmacovigilance resources for the ambulatory care setting: enhancing patient safety. Hosp. Pharm. 2014;49:363–8.

[77]Parker RM, et al. Risk of confusion in dosing tamiflu oral suspension in children. New Engl. J. Med. 2009;361:1912–3.