brand-name drug,[4] and it must generally have the same active ingredient(s), route of administration, dosage form, strength, use indications, and labeling information as the existing medication.[5] Disputes over these characteristics become the battleground for many of the games that are played between brand-name companies and generics, so we believe it is important to provide a few definitions before moving forward.

- Active ingredient: the ingredient in a medication that actually affects the state of the body. For example, in a capsule of omeprazole (Prilosec), an acid reducer, the shell of the capsule contains ingredients such as gelatin, butyl alcohol, and food dyes, but the only active ingredient is omeprazole. Generic drugs are commonly referred to only by their active ingredients.
- Route of administration: how the drug is introduced or absorbed into the body. An omeprazole capsule is classified by the FDA as having an "oral" route of administration, unsurprisingly referring to the fact that the medication is swallowed. Other common routes of administration, as classified by the FDA, include "injection," "intravenous," "topical," and "nasal."
- Dosage form: how the drug is packaged for use or consumption. Common dosage forms include tablets, capsules, suspensions (liquids), solutions (for injection or intravenous use), sprays, gels, films, ointments, and lotions, but less common forms are also seen, including lozenges, suppositories, and even shampoos.
- Strength: how much of the active ingredient is contained within a unit of the medication. Strength is often referenced when discussing varying capsules or tablets – 25 mg tablets, 50 mg capsules, and so on. Other strengths are more complicated (*e.g.* "3 mg/mL of active ingredient in an intravenous solution").
- Use indications: the officially stated and approved uses of the medication. A drug may be approved, for example, to treat anxiety or to relieve pain following surgery. The FDA keeps an official list of "use codes" delineating uses of medications connected to patents – literally thousands exist.
- Labeling information: any other information on a drug's label or prescribing information. Examples include warnings such as "this drug should not be taken with alcohol" and information about how the medication should be taken (*e.g.* "once a day with a high-fiber meal").

Once the generic can demonstrate these characteristics, however, the remainder of the approval process is significantly streamlined in comparison to approval of

[4] The Act Defines two drugs as bioequivalent when "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." 21 U.S.C. § 355(j)(8)(B) (2012).

[5] 21 U.S.C. § 355(j)(2)(A) (2012).