Table 10.1 The FDA BsUFA Fee Structure for 2016

Category	Stage/Type	Fee
BPD	Initial	$237,420
	Annual	$237,420
Application	With clinical studies	$2,374,200
	Without clinical studies	$1,187,100
Supplement	With clinical studies	$1,187,100
Product		$114,450
Establishment		$585,200
Reactivation		$474,840

Source: FDA, http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm.

not all applications require a clinical trial—and that is one mind-set of the FDA that must be clear to all. Unfortunately, the biosimilar product industry is being populated with scientists and administrators from the big pharma, to whom the thought of getting a biological product approved without a massive clinical trial is unthinkable. If you take a look at ClinicalTrials.gov and figure out who is doing what, you will find that all deep-pocket sponsors still continue doing clinical trials; the argument in favor of clinical trials comes from the marketing teams, who still have to understand how to present their product to clinicians and other stakeholders without clinical trials.

The FDA has also released data on its workload in handling biosimilar applications (Table 10.2). It also provides its workload summary (Table 10.3). These data show us how the FDA sees the future of biosimilars approval, the competition in making, and how the FDA sees the workload to review these applications.

10.5 The future

In 2005, I wrote my first book on this subject and titled it *Handbook of Biogeneric Therapeutic Proteins*, hoping that *biogeneric* would stick—a subliminal message to regulatory agencies—it did not. Instead, we have the universally accepted *biosimilar*. However, only the FDA has created a category of interchangeable biosimilar products, which is quite akin to biogeneric, legal subtleties notwithstanding. A few years ago, "product by the process" was the mantra of the originator companies; that is blown away. A few years from today, all uncertainty about the safety and effectiveness of biosimilars will be gone, and the market for these products will take a more generic stance. However, given that the cost of regulatory filing with the FDA will remain high, there is not going to be a crowding of players in these markets. The FDA will continue to push the scientific envelope, and the sponsors of biosimilars who will