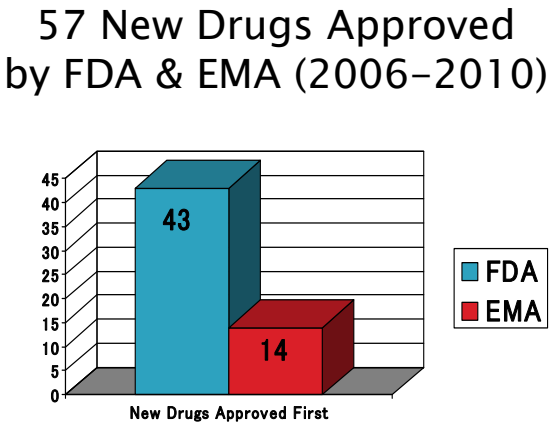
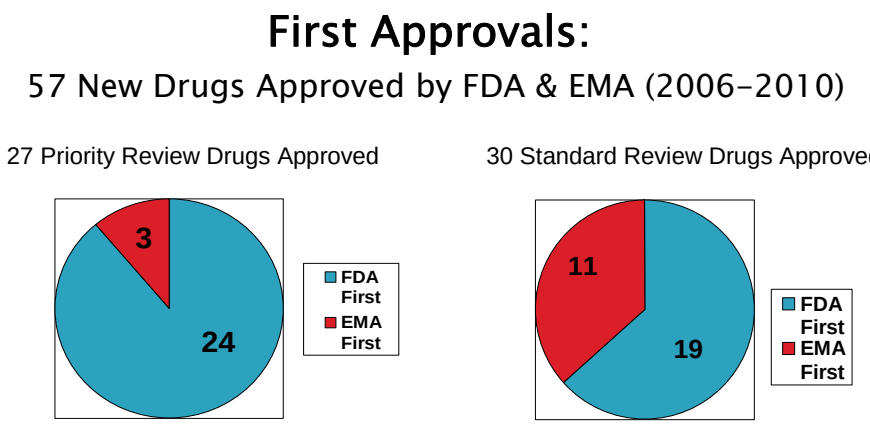
Is the U.S. really slower than Europe in approving new drugs?

FDA often hears claims that the U.S. approves new drugs less quickly than other regulatory agencies, particularly the European Medicines Agency (EMA). This is not true; in many cases, FDA gets a drug on the market faster than does Europe. For example, FDA recently compared marketing approval of 57 novel drugs approved by both FDA and E.U. regulators from 2006 through 2010. The chart below shows that FDA approved the majority of these products before the EMA..



2 out of 3 new applications were approved by FDA first

When a potential new drug represents a "therapeutic advance" (i.e., a new important medical use), FDA designates that drug with a priority review, so it can be evaluated faster than other drugs. Drugs that are not designated priority review are designated standard review. Twenty-seven of the 57 drugs approved by both FDA and EMA were FDA-designated priority review drugs. The chart below shows that FDA was first to approve approved more priority and standard review drugs than the EMA.

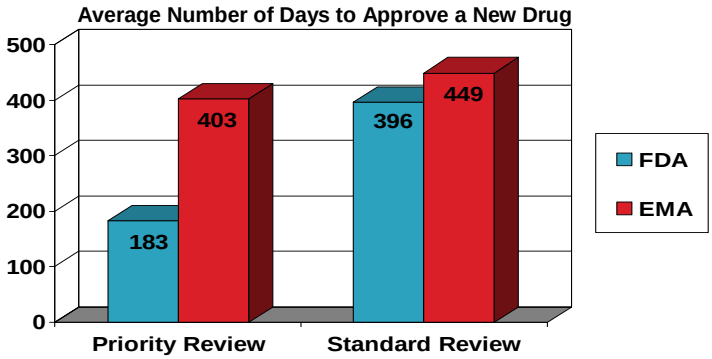


FDA Approved Drugs First for:

- 88% of priority review drugs
- 58% of standard review drugs

In addition to being first to approve most of the 57 drugs approved by both FDA and EMA, FDA lso took less time, on average, to approve these new products. The chart below shows FDA had faster average approval times for both priority and standard review drugs.

Average Timeline for FDA & EMA Drug Approvals (2006-2010)



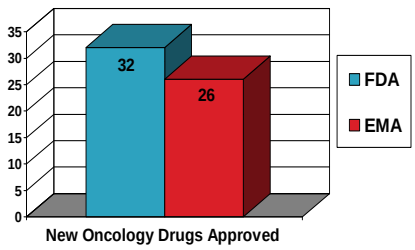
FDA drug approval timeline average..

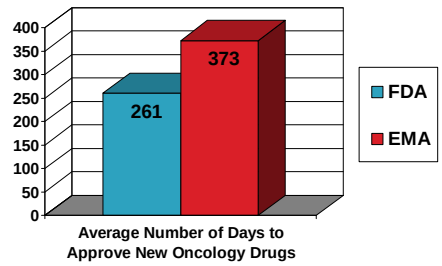
- 53 days faster than EMA for standard review drugs
- 220 days faster than EMA for priority review drugs (more than twice as fast)

Of any drug class, cancer drugs are among those that need the fastest approvals and highest priority. FDA analyzed 35 applications for new cancer drugs approved by FDA or EMA from FY 2003 through 2010. The chart below shows that of these 35 products considered by both agencies, FDA approved more new drugs and approved them in less time than the EMA.

FDA Approved More Cancer Drugs

35 new oncology drugs approved by either FDA or EMA



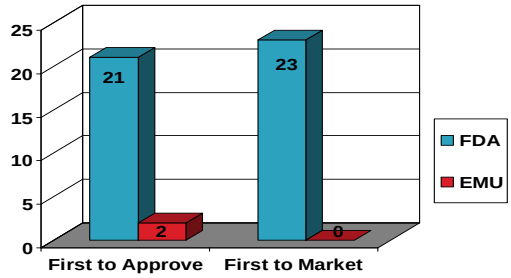


- FDA approved most of these products in 6-12 months
- EMA approved most of these products in 11-14 months

Twenty-three of the 35 cancer drugs were approved by both agencies. The chart below shows that FDA was first to approve most of those 23 products and in each case, enabled them onto the U.S. market sooner than EMA enabled its approved products to market.

FDA Approved Cancer Drugs Faster than EMA

23 new cancer drugs were approved by *both* FDA & EMA



- Of 23 new cancer drugs approved by both FDA and EMA, FDA approved 21 first
- All 23 came to the U.S. market before they reached the European market

FDA is not in a "race" with other countries. However, we recognize it is our public health duty to approve drugs as quickly and safely as possible.