

Comparison of the Drug and Device Approval Process

Industry Variables	Drugs (CDER data)	Medical Devices (CDRH data)
U.S. Market size (2004)	\$222 billion	\$80 billion (includes medical supplies)
Average product lifetime	decades	years
Special incentives for development	Market exclusivity after approval (determined by FDA), patent extension for regulatory process (determined by Patent office), pediatric exclusivity, orphan drug process for rare diseases, waived fees for certain types of submissions (agency defined).	Patent extension for regulatory process (determined by Patent office) Humanitarian device exemption for rare diseases, no pediatric exclusivity, but waived fees for certain types of submissions (such as pediatric studies, agency defined).
FDA Variables		
Premarket review	Required for all drugs	Some devices exempt
Type of submission and 2005 user fees	<p>Not dependent on risk to patient</p> <ul style="list-style-type: none"> ○ NDA (new drug application), ○ ANDA (abbreviated new drug application) for generic drugs. <p>User fees:</p> <ul style="list-style-type: none"> ○ \$672,000 for an application requiring clinical data, ○ \$336,000 for an application not requiring clinical data or a supplement requiring clinical data ○ \$262,200 (establishment fees) ○ \$41,710 (product fees) 	<p>Dependent on risk-based classification;</p> <ul style="list-style-type: none"> ○ PMA for high risk devices (\$239,237, standard; \$90,910 for small business). ○ 510(k) for low/moderate risk devices (\$3,502 standard; \$2,802 for small business).
Total number of submissions, all types, in 2003	2,104 received, 2,019 decisions made (a)	9,872 received; 9,570 completed; 4,740 decisions made (b)
Total number of submissions, all types, Approved/cleared in 2003	1,641 (2,019)	4,292 (4,740)

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Total number of submissions, all types, Approvable, in 2003	249 (2,019)	115 (4,740)
Total number of submissions, all types, Not approvable in 2003	79 (2,019)	63 (4,740)
Total number of submissions, all types, Withdrawn (drugs) Not approved (devices) in 2003	50 (2,019)	270 (4,740)
Standard for approval	NDA, Efficacy supplements: safety and effectiveness ANDA: bioequivalence	PMA, de novo 510(k): safety and effectiveness other 510(k)s: substantial equivalence.
Types of studies	<i>Safety and effectiveness:</i> preclinical and interventional clinical trials often done; data from at least one controlled clinical trial may suffice; approval can be granted based on a surrogate endpoint (21 CFR § 314.510), however, approval under this section is subject to postmarket studies to verify clinical benefit <i>Bioequivalence:</i> requires demonstration that the generic form of an original drug, used at the same dose intended for the same population, delivers active ingredient in the same amount at the same rate. Summaries of approved applications available on website.	<i>Safety and effectiveness:</i> preclinical and interventional clinical trials done for implantable or life-sustaining devices may investigate clinical outcome), if a 'next generation' studies endpoints are a surrogate marker of disease or health; interventional trial rarely done for diagnostic devices; <i>Substantial equivalence:</i> comparison of device performance to another legally marketed device using clinical or analytical samples. Summaries of approved/cleared applications available on website
FDA Average Review time (days), 2003	NDA: 231 (priority, i.e., significant improvement), 357 (standard) ANDA: 510	PMA: 151 510(k): 76

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Postmarket surveillance	MedWatch: searchable webpage for medical product safety information	MedWatch: searchable webpage for medical product safety information
Adverse Event Reporting (time indicates days after becoming aware of an incident)	<p>Manufacturers report to FDA:</p> <ul style="list-style-type: none"> ○ Serious and unexpected events within 15 calendar days ○ Individual reports available on website, but difficult to search 	<p>Manufacturers report to FDA:</p> <ul style="list-style-type: none"> ○ Deaths, serious injuries, malfunctions within 30 calendar days ○ Serious events requiring remedial action: 5 working days <p>User facilities report to FDA:</p> <ul style="list-style-type: none"> ○ Death & serious injury: within 10 working days ○ Individual reports available on website (Medical Device Reporting database)
Number of reports received, 2003	<p>370,887:</p> <ul style="list-style-type: none"> ○ 22,955 MedWatch reports directly from individuals ○ 144,310 manufacturer 15-day (expedited) reports ○ 58,998 serious manufacturer periodic reports ○ 144,624 nonserious manufacturer periodic reports 	<p>64,369:</p> <ul style="list-style-type: none"> ○ 60,767 individual medical device adverse event reports from manufacturers, user facilities, and importers, and ○ 3,602 voluntary reports from health care professionals and the public
Tracking	Not required	Required for implantable, life-sustaining or other high risk devices as defined
Number safety-based market withdrawals in 2003	0	5