Food and Drug Administration

Changes to FY 2007 Performance Targets

Given that final FY 2007 appropriation levels were unknown at the time the Food and Drug Administration developed the performance targets for the FY 2008 Congressional Justification, the FY 2007 targets were not modified to reflect changes in the budget. The following contains FY 2007 performance targets that have been modified to reflect final FY 2007 appropriations. These updated targets will be used for official reporting purposes.

FDA Performance Goals with FY 07 RCR Targets

Foods Performance Goals

Long Term Goal: Prevent harm from regulated products by increasing the likelihood of detection and interception of substandard manufacturing processes and products, through efficient and effective risk targeting, external partnering and collaboration.

Measure	FY	Target	Result
8. Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020) (output)	*2008*	5,700	01/09
	2007	**5,625***	**01/08**
	2006	5,963	6,795
	2005	6,490	7,568
	2004	6,840	7,597
	2003	6,650	7,363
	2002	6,650	7,442

Data Source: Field Data Systems.

Data Validation: ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.

Cross Reference: These performance measures support HHS Strategic Goal 2. Performance measure 8 supports Healthy People 2010 Objectives.

Note:
*** The FY 07 final appropriation level was higher than anticipated, therefore the FY 07 targets have been adjusted.**

Human Drugs Performance Goals

Long Term Goal: Sustain availability of safe and effective new and generic products by improving rapid, transparent, and predictable science-based review of marketing applications.

Measure	FY	Target	Result
3. Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans. (12003) (Output) (Formerly: Ensure safe and effective generic drugs are available to the public.) FY 07 and 08 Measures: Complete review and action upon fileable original generic drug applications within 6 months after submission date, excluding first cycle approvals. FY 06 Measure: Number of months of the average FDA time to approval or tentative approval for the fastest 25% of original generic drugs application.	*2008*	70% of an estimated 700 applications	5/09
	2007	**55% of an estimated 700 applications****	**5/08**
	2006	Fastest 25% by .5 mos	5/07
FY 05 Measure: Complete review and action upon fileable original generic drug applications within 6 months after submission date.	*2005*	90%	66% of 766
	2004	85%	87% of 543
	2003	80%	90% of 423
	2002	65%	85% of 339

Data Source: Review performance monitoring is being done in terms of cohorts, e.g., FY 2003 cohort includes applications received from October 1, 2002, through September 30, 2003. CDER uses the Center-wide Oracle Management Information System (COMIS) and New Drug Evaluation/Management Information System (NDE/MIS). FDA has a quality control process in place to ensure the reliability of the performance data in COMIS.
The Pediatric Exclusivity Database tracks all data regarding pediatric exclusivity as mandated by FDAMA and reauthorized by BCPA. Specifically, this database tracks the number of WRs issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made. The Pediatric Page database captures all information regarding waivers, deferrals, and completed studies for applications that are subject to the Pediatric Research Equity Act.
Published monographs that establish acceptable ingredients, doses, formulations, and consumer labeling for OTC drugs.

Data Validation: The Center-wide ORACLE Management Information System (COMIS) is CDER's enterprise-wide system for supporting premarket and postmarket regulatory activities. COMIS is the core database upon which most mission-critical applications are dependent. The type of information tracked in COMIS includes status, type of document, review assignments, status for all assigned reviewers, and other pertinent comments. CDER has in place a quality control process for ensuring the reliability of the performance data in COMIS. Document room task leaders conduct one hundred percent daily quality control of all incoming data done by their IND and NDA technicians. Senior task leaders then conduct a random quality control check of the entered data in COMIS. The task leader then validates that all data entered into COMIS are correct and crosschecks the information with the original document.
CDER uses the Pediatric Exclusivity database and the Pediatric Research Equity Act Tracking System (PREATS) to track information such as number of written requests issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made as well as information related to the PREA legislation.

Cross Reference: These performance measures support HHS Strategic Goal 2.

Note:
**** The final FY 07 appropriation level was approximately equal to the FY 07 President's Budget, and higher than the level FDA anticipated under the FY07 Continuing Resolution. However, the number of generic drug application receipts has far out paced staffing increases, so the goal was dropped from the FY 07 President's Budget level of 60% to 55% in FY 07.**

Biologics Performance Goals

Long Term Goal: Sustain access to safe and effective new products by providing rapid, transparent and predictable science-based review of marketing applications.

Measure	FY	Target	Result
3. Complete review and action on complete blood bank and source plasma BLA submissions, and BLA supplements within 12 months after submission date. (13005) Measure 3A: Percentage of BLA Submissions within 12 months. (Output)	*2008*	50%	11/09
	2007	**90%***	**11/08**
	2006	90%	11/07
	2005	90%	100% of 4
	2004	90%	100% of 1
	2003	90%	100% of 5
	2002	90%	100% of 5
Measure 3B: Percentage of BLA Supplements within 12 months. (Output)	*2008*	75%	11/09
	2007	**90%***	**11/08**
	2006	90%	11/07
	2005	90%	100% of 401
	2004	90%	100% of 542
	2003	90%	100% of 530
	2002	90%	99% of 469

Long Term Goal: Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products.

Measure	FY	Target	Result
5. Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. (13012) Measure 5A: The number of inspections conducted of the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments including the annual inspection of vaccine manufacturers. (output)	*2008*	1,175	1/09
	2007	**1,138***	**01/08**
	2006	1,128	1,292
	2005	1,257	1,392
	2004	1,319	1,444
	2003	1,331	1,594
	2002	1,331	1,419
Measure 5B: The number of human tissue inspections conducted to enforce the new regulations. (output)	*2008*	325	01/09
	2007	325	01/08
	2006	250	354
	2005	NA	NA

Data Source: CBER's Regulatory Management System and Field Data Systems.

Data Validation: The Center for Biologics Evaluation and Research (CBER) uses various databases to manage its diverse programs and to assess performance. The principal CBER database is the Regulatory Management System-Biologics License Application (RMS-BLA). The RMS-BLA is CBER's new VAX-based, Oracle database that is used to track all biologics license applications, and supplement submissions; provide information to facilitate the review process (product, application status, milestone tracking, facility, review committee, industry contacts, and other information); and produce a wide variety of management reports. The Regulatory Information Management Staff (RIMS) monitors and is responsible for maintaining data quality and integrity in RMS-BLA.

The Biologics Investigational New Drug Management System (BIMS) is CBER's VAX-based, Oracle database that is used to track all Investigational New Drug Applications (IND), Investigational Device Exemption (IDE), and Master Files (MF) submissions; provide product, application status, and other information to facilitate the review process; and produce a wide variety of management reports. There are numerous mechanisms established for quality control in Document Control Center, the application review offices, the Regulatory Information Management Staff, and several built into BIMS itself.

The Blood Logging and Tracking System (BLT) records and tracks the various applications reviewed by the Office of Blood Research and Review. The Office also has an NDA tracking system. The data retrieved

from these systems are reviewed and validated by the RIMS and the application review offices. If errors are detected, they are corrected.
Federal regulations (21 CFR, Part 600.14 and 606.171) require reporting of deviations in the manufacture of biological products that affect the safety, purity, or potency of the product. The Biological Product Deviation Reports (BPDRs) (previously called error and accident reports) enable the Agency to evaluate and monitor establishments, to provide field staff and establishments with trend analyses of the reported deviations and unexpected events, and to respond appropriately to reported biological product deviations to protect the pubic health
The Biologics Program relies in the Office of Regulatory Affairs' Field Accomplishments and Tracking System (FACTS) to register and record biologics manufacturing establishment inspection and compliance data. FACTS versions 1 and 2 together will replace the several dozen applications that comprise the current Field Information System (FIS).

Cross Reference: These performance measures support HHS Strategic Goal 2.

Note:
*** The FY 07 final appropriation level was higher than anticipated, therefore the FY 07 targets have been adjusted.**

Animal Drug and Feeds Performance Goals

Long Term Goal: Increase access to safe and effective veterinary products, and to safe and nutritious food products, including products for unmet animal and human health needs.

Measure	FY	Target	Result
1. Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (14020) (output) Measure: Complete review and action on original NADAs & reactivations of such applications received during FY 2008.	*2008*	90% w/in 180 days	01/10
	2007	**90% w/in 200 days***	**01/09**
	2006	90% w/in 230 days	01/08
	2005	90% w/in 270 days	100%
	2004	90% w/in 295 days	100%
	2003	NA	NA

Data Source: Submission Tracking and Reporting System (STARS).

Data Validation: STARS tracks submissions, reflects the Center's target submission processing times and monitors submissions during the developmental or investigational stages and the resulting application for marketing of the product.

Cross Reference: This performance measure supports HHS Strategic Goal 2.

Long Term Goal: Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products.

2. Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009) Measure 10A: The number of inspections conducted of registered animal drug and feed establishments. (output)	*2008*	620	01/09
	2007	**620***	**01/08**
	2006	618	699
	2005	688	772
	2004	703	773
	2003	721	847
	2002	720	804

Data Source: Field Data Systems.

Data Validation: ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.

Cross Reference: This performance measure supports HHS Strategic Goal 2.

Note:
*** The FY 07 final appropriation level was higher than anticipated, therefore the FY 07 targets have been adjusted.**

Medical Devices Performance Goals

Long Term Goal: Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.

Measure	FY	Target	Result
1. Percentage of Expedited PMAs reviewed and decided upon within 300 days; Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days. (15033) (Outcome) *Measure 1A*: Percentage of Expedited PMAs reviewed and decided upon within 300 days. Goal is based on FDA Review Days. See note at the end of the table.	*2008*	90%	9/10
	2007	**90%***	**9/09**
	2006	80%	9/08
	2005	70%	9/07
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
Measure 1B: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days. (Outcome) Goal is based on FDA Review Days. See note at the end of the table.	*2008*	90%	9/10
	2007	**90%***	**9/08**
	2006	80%	95% of 51 applications
	2005	NA	NA
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
2. Percentage of 180 day PMA supplements reviewed and decided upon within 180 days. (15031) (Outcome) Goal is based on FDA Review Days. See note at the end of the table.	*2008*	90%	1/10
	2007	**90%***	**1/09**
	2006	80%	95% of 131 applications
	2005	80%	95% of 101 applications
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
3. Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 days. (15032) (Outcome) Goal is based on FDA Review Days. See note at the end of the table.	*2008*	80%	9/09
	2007	**80%***	**9/08**
	2006	75%	9/07
	2005	75%	92% 3,376 applications
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA

Data Source: CDRH Premarket Tracking System and Receipt Cohorts and Field Data Systems.

Data Validation: To help ensure Agency consistency in tracking and reporting Premarket activities, CDRH utilizes the Premarket Tracking System, which contains various types of data taken directly from the Premarket submissions. FDA employs certain conventions for monitoring and reporting performance; among these are groupings of Premarket submissions into decision and receipt cohorts. Decision cohorts are groupings of submissions upon which a decision was made within a specified time frame, while receipt cohorts are groupings of submissions that were received within a specified time frame. The Premarket performance goals are based on receipt cohorts. Final data for receipt cohorts are usually not available at the end of the submission year. Because the review of an application received on the last day of the submission year, e.g., a PMA with 180 day time frame, may not be completed for at least 6 months or longer, final data for the submission or goal year may not be available for up to a year or more after the end of the goal year.

Cross Reference: These performance measures support HHS Strategic Goal 2.

Note:
*** The FY 07 final appropriation level was higher than anticipated, therefore the FY 07 targets have been adjusted.**

NOTE: The MDUFMA review goals are based on FDA review time only, and do not include time that elapses when the sponsor is responding to questions or issues raised by FDA. This means that FDA cannot determine exactly when all the applications in a review cohort will be completed. The actual results reported for this goal are as of the times noted, and as the final applications in the cohort are resolved, small changes to previously reported results may occur.

Long Term Goal: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.

Measure	FY	Target	Result
7. Focus inspectional coverage on device firms to ensure consumers are protected and that the public health is advanced. FY06 Measure: Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005) (output) FY 05 Measure: Utilize Risk management to target inspection coverage for Class II and Class III domestic medical device manufacturers.	*2008*	1,270	01/09
	2007	**1,195***	**01/08**
	2006	1,234	1,299
	2005	1,104	1,265
	2004	1,110	1,414
	2003	1,080	1,428
	2002	1,049	1,062

Data Source: Mammography Program Reporting and Information System (MPRIS)

Data Validation: The Mammography Program Reporting and Information System (MPRIS) is a set of applications used to support all aspects of the FDA implementation of the Mammography Quality Standards Act of 1992. This includes the collection, processing and maintenance of data on mammography facility accreditation and certification, FDA inspections and compliance actions. MPRIS is envisioned as a centralized repository of information that supports FDA's mission to improve the quality of mammography and improves the overall quality, reliability, integrity, and accessibility of facility certification, inspection, and compliance data by eliminating multiple versions of the data while expanding and automating data edits, validation, and security of a single integrated database.

Cross Reference: These performance measures support HHS Strategic Goal 2.

Long Term Goal: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.

Measure	FY	Target	Result
8. Protect the public health by monitoring adverse events through the MedSun Network. (15012) (Outcome)	*2008*	Increase the participation rate of facilities in the MedSun network to 95%	1/09
	2007	**Increase the participation rate of facilities in the MedSun network to 90% ***	**1/08**

	2006	Expand actively participating sites in MedSun Network to 71% & maintain cohort of 350 facilities.	Expanded actively participating sites in MedSun Network to 86% & maintain a cohort of 350 facilities.
	2005	350 facilities	354 facilities
	2004	240 facilities	299 facilities
	2003	180 facilities	206 facilities
	2002	80 facilities	80 facilities
Data Source: CDRH Adverse Events Reports			
Data Validation: FDA's adverse event reporting system's newest component is the Medical Device Surveillance Network, MedSun program. MedSun is an initiative designed both to educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse events, medical errors and other problems to FDA and/or the manufacturer, and to ensure that new safety information is rapidly communicated to the medical community thereby improving patient care.			
Cross Reference: This performance measure supports HHS Strategic Goal 5.			
Note: *** The FY 07 final appropriation level was higher than anticipated, therefore the FY 07 targets have been adjusted.**			

Combined ORA Performance Goals

(These goals are repeated here to give a cohesive look at ORA)

Long Term Goal: Prevent harm from regulated products by increasing the likelihood of detection and interception of substandard manufacturing processes and products, through efficient and effective risk targeting, external partnering and collaboration.

Measure	FY	Target	Result
6. Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020) (output)	*2008*	5,700	01/09
	2007	**5,625***	**01/08**
	2006	5,963	6,795
	2005	6,490	7,568
	2004	6,840	7,597
	2003	6,650	7,363
	2002	6,650	7,442
9. Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. (13012) Measure 9A: The number of inspections conducted of the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments including the annual inspection of vaccine manufacturers. (output)	*2008*	1,175	1/09
	2007	**1,138***	**01/08**
	2006	1,128	1,292
	2005	1,257	1,392
	2004	1,319	1,444
	2003	1,331	1,594
	2002	1,331	1,419
10. Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009) Measure 10A: The number of inspections conducted of registered animal drug and feed establishments. (output)	*2008*	620	01/09
	2007	**620***	**01/08**
	2006	618	699
	2005	688	772
	2004	703	773
	2003	721	847
	2002	720	804
11. Focus inspectional coverage on device firms to ensure consumers are protected and that the public health is advanced. FY06 Measure: Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005) (output) FY 05 Measure: Utilize Risk management to target inspection coverage for Class II and Class III domestic medical device manufacturers.	*2008*	1,270	01/09
	2007	**1,195***	**01/08**
	2006	1,234	1,299
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Data Validation: ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.

Cross Reference: These performance measures support HHS Strategic Goal 2. Performance measure 6 supports

Healthy People 2010 Objectives.
Note: *** The FY 07 final appropriation level was higher than anticipated, therefore the FY 07 targets have been adjusted.**