Actions and Reports with a Due Date Specified by the Medical Device User Fee and Modernization Act of 2002
and the Medical Devices Technical Corrections Act

Includes Actions Required by Regulations and Notices Issued to Implement MDUFMA

Updated September 7, 2004

(✓ indicates the requirement has been met. Hyperlinks lead to PDF versions of cited reference.)

Date Due (Time beyond Effective Date)	**By**	**Requirement**	**Citation** (to FD&C Act, where possible)
October 1, 2002 — Medical device premarket submissions made on or after this date are subject to fees. Section 738(a)(1)(A). **October 26, 2002 — MDUFMA signed by President, becomes law. This is the effective date of most provisions of the act.**			
December 25, 2002 (60 days) ✓	FDA	FDA must establish an Office (within the Office of the Commissioner) to coordinate and monitor the review of combination products. [December 24, 2002 — FDA established the Office of Combination Products within the Office of International Activities and Strategic Initiatives in the Office of the Commissioner.]	503(g)(4)(A)
March 31, 2003 ✓	GAO	GAO must submit a report determining the amount obligated during FY 2002 for medical device compliance activities. [August 30, 2004 — GAO's report is available at — www.fda.gov/cdrh/mdufma/reports/gao-04-1022.pdf.]	704(g)(10)(B)
April 1, 2003 (date set by Notice) — Beginning this date, if a medical device application is subject to a user fee, the fee must be paid at the time the application is submitted to FDA. See 68 F.R. 8773 (February 25, 2003). If the fee is not paid, the application "shall be considered incomplete and shall not be accepted for filing . . . until all fees owed . . . have been paid." See section 738(f).			
April 24, 2003 (180 days) ✓	FDA	Publish criteria for the accreditation of third-parties to conduct inspections of class II and class III device manufacturers. [April 28, 2003 — FDA announced the criteria it will use to accredit persons for the purpose of conducting inspections of eligible device manufacturers under section 704(g). See 68 F.R. 22400.]	704(g)(2)
April 24, 2003 (180 days) ✓	NIH	NIH must submit to Congress a report describing research on breast implants being conducted or supported by NIH. [July 16, 2003 — Report available at www4.od.nih.gov/orwh/implants.pdf]	MDUFMA Sec. 214(a)

Date Due (Time beyond Effective Date)	**By**	**Requirement**	**Citation** (to FD&C Act, where possible)
April 26, 2003 (Six months) ✓	FDA	FDA must identify the types of reprocessed single-use devices for which 510(k)s will be required in the future, and must publish a list of those devices in the *Federal Register*. 510(k)s for these devices must include "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of time the device is reprocessed as intended" by the person who submits the 510(k). Section 510(o)(1)(A). Publication of this list also triggers the time frame for submission of validation data for devices on this list that *already have* a 510(k); see below at January 26, 2004. [April 30, 2003 — FDA published a list of reprocessed single-use devices for which validation data is required. See 68 F.R. 23139. Also see the following item.]	510(o)(1)(A)
April 26, 2003 (Six months) ✓	FDA	FDA is to review the types of *critical* reprocessed single-use devices that are currently exempt from 510(k), and determine which of these exemptions is to be terminated. FDA must publish a *Federal Register* notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list. [April 30, 2003 — FDA published a list of critical reprocessed single-use devices whose exemption from premarket notification is revoked and for which validation data is required. See 68 F.R. 23139. Also see the preceding item.] [June 26, 2003 — FDA added nonelectric biopsy forceps to the list of critical reprocessed single-use devices whose exemption from 510(k) is revoked and for which validation data is required. See 68 F.R. 38071.]	510(o)(2)
April 26, 2003 (Six months) ✓	FDA	FDA must modify MedWatch forms to facilitate reporting of information relating to reprocessed single-use devices. [April 29, 2003 — Proposed collection of information submitted to Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. See 68 F.R. 22716.] [October 6, 2003 — OMB approved FDA's revised MedWatch forms (for voluntary reporting: Form FDA 3500; for mandatory reporting: Form FDA 3500A). FDA is permitting continued use of the existing forms to allow industry time to make changes to computerized reporting systems. See 68 F.R. 58691.]	MDUFMA Sec. 303
July 1, 2003 ✓	GAO	*If* appropriations for FY 2003 are below a certain amount, GAO must report to Congress concerning "whether and to what extent [FDA] is meeting the performance goals identified for [FY 2003]" and whether FDA will meet future performance goals. [August 30, 2004 — GAO's report is available at — www.fda.gov/cdrh/mdufma/reports/gao-04-1022.pdf.]	738(g)(1)(A)(ii)(II)

Date Due (Time beyond Effective Date)	**By**	**Requirement**	**Citation** (to FD&C Act, where possible)
July 23, 2003 (270 days) ✓	FDA	FDA must issue guidance on information necessary to assure the safety and effectiveness of pediatric devices, and on protections for children in clinical trials of pediatric devices. [July 24, 2003 — FDA released draft guidance *Premarket Assessment of Pediatric Medical Devices*. This draft guidance discusses the type of safety and effectiveness information needed to support marketing of pediatric devices and measures to be used to help protect pediatric patients (newborns through adolescents up to age 21) during clinical trials of pediatric devices. See 68 F.R. 43729.]	MDUFMA Sec. 213
August 2, 2003 ✓	FDA	Fees for FY 2004 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year. [August 1, 2003 — FDA published a notice of the fees to be assessed for medical devices applications received during FY 2004. See 68 F.R. 45246.]	738(c)(5)
October 1, 2003 — New fee schedule for FY 2004 applications goes into effect. Reduced 510(k) fee for small business goes into effect.			
October 26, 2003 (One year) ✓	FDA	FDA must accredit third-parties to conduct establishment inspections; an eligible establishment would then be permitted to select any accredited person to conduct an inspection in lieu of an FDA inspection. [October 24, 2003 — FDA published a list of 15 persons accredited to conduct third-party inspections. The list is available at — www.fda.gov/cdrh/ap-inspection/ap-inspection.html#list] [November 6, 2003 — FDA published a *Federal Register* notice announcing the availability of the list of persons accredited to conduct inspections. See 68 F.R. 62811.]	704(g)(1)
October 26, 2003 (One year) ✓	FDA	FDA must report to Congress on the "timeliness and effectiveness" of device reviews by centers *other than CDRH*. The report is to include recommendations on whether responsibility for regulating such devices should be reassigned within FDA. [FDA's report to Congress is available at — www.fda.gov/cber/mdufma/report0803.pdf.]	MDUFMA Sec. 205
October 26, 2003 (One year, and annually thereafter) ✓	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products. *Note:* Beginning in 2004, this report will be submitted by the end of the calendar year, and will report on activities for the preceding fiscal year. This is consistent with the approach used for other FDA reports. [FDA's report to Congress is available at — www.fda.gov/oc/combination/Congressreport.pdf.]	503(g)(4)(G)

Date Due (Time beyond Effective Date)	**By**	**Requirement**	**Citation** (to FD&C Act, where possible)
November 30, 2003 ✓	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (during FY 2003). This report is due no later than 60 days after the end of each fiscal year. [FDA's report to Congress is available at — www.fda.gov/cdrh/mdufma/fy2003performance.pdf,]	MDUFMA Sec. 103
December 3, 2004 (date set by Federal Register Notice) — First Annual Stakeholder Meeting on Implementation of MDUFMA. See 68 F.R. 55967 (September 29, 2003).			
January 26, 2004 (15 months) — Requirement for labeling of reprocessed single-use devices becomes effective. Section 502(v)(2).			
January 30, 2004 (date set by Notice) — Holders of 510(k)s for reprocessed devices included on the list published by FDA pursuant to section 510(o)(1)(A) (see entry at April 26, 2003) must submit validation data to FDA. Section 510(o)(1)(B). See 68 F.R. 23139 (April 30, 2003).			
January 31, 2004 ✓	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2003). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103
April 26, 2004 (18 months, at most) — Expiration of limit on number of persons who can be accredited to conduct inspections. In the first year following publication of accreditation criteria (see entry at April 24, 2003), FDA may accredit no more than 15 persons. Section 704(g)(2).			
April 26, 2004 (18 months) ✓	FDA	FDA is to review the types of *semi-critical* reprocessed single-use devices that are currently exempt from 510(k), and determine which of these exemptions is to be terminated. FDA must publish a *Federal Register* notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list.	510(o)(2)
July 1, 2004 ✓	GAO	*If* appropriations for FY 2004 are below a certain level, GAO must report to Congress concerning "whether and to what extent [FDA] is meeting the performance goals identified for [FY 2004]" and whether FDA will meet future performance goals. [August 30, 2004 — GAO's report is available at — www.fda.gov/cdrh/mdufma/reports/gao-04-1022.pdf.]	738(g)(1)(A)(ii)(II)
July 30, 2004 (date set by Notice;) — 510(k)s are required for critical reprocessed single use devices whose exemption from 510(k) has been revoked. See 68 F.R. 23139 (April 30, 2003). *Note: 510(k)s for nonelectric biopsy forceps are due September 27, 2004; see 68 F.R. 38071 (June 26, 2003).*			
August 2, 2004 ✓	FDA	Fees for FY 2005 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year. [August 2, 2004 — FDA published a notice of the fees to be assessed for medical devices applications received during FY 2004. See 69 F.R. 46153.]	738(c)(5)
September 28, 2004 (180 days after enactment of MDTCA)	FDA	FDA must submit a report to Congress concerning barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children.	MDTCA Sec. 3

Date Due (Time beyond Effective Date)	By	Requirement	Citation (to FD&C Act, where possible)
October 1, 2004 — Authority for third-party establishment inspections may be suspended for FY 2005 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).			
November 30, 2004	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (through FY 2004). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
December 31, 2004 (Annual Report for FY 2004)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
January 31, 2005	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2004). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103
July 1, 2005	GAO	*If* total appropriations for FY 2003 - FY 2005 are below a certain level, GAO must report to Congress concerning "whether and to what extent [FDA] is meeting the performance goals identified for [FY 2005], and whether FDA will be able to meet all performance goals identified for fiscal year 2006."	738(g)(1)(B)(ii)(II)
August 2, 2005	FDA	Fees for FY 2006 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.	738(c)(5)
October 1, 2005 — User fee authority may be suspended for FY 2006 if appropriations for FY 2003 through FY 2006 are less than an amount specified by the act. Section 738(g)(1)(C). **October 1, 2005 — Authority for third-party establishment inspections may be suspended for FY 2006 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).** **October 26, 2005 (36 months) — Requirement for a device to conspicuously bear the name of its manufacturer becomes effective. Section 502(u).** (Under MDUFMA section 301(b), the effective date of this provision was originally April 26, 2004; section 2(c)(1) of the Medical Devices Technical Corrections Act extended the effective date to October 26, 2005.) *Note:* FDA does not intend to object if a manufacturer has not fully implemented the requirements of this provision for up to 18 months after FDA issues a final guidance on its interpretation and implementation of section 502(u). See 68 F.R. 37161 (June 23, 2003).			
November 30, 2005	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (through FY 2005). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
December 31, 2005 (Annual Report for FY 2005)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
January 31, 2006	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2005). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103

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July 31, 2006	FDA	FDA must hold a public meeting to consult with stakeholders and determine whether it is appropriate to implement certain FY 2007 decision goals. If FDA determines a goal is not appropriate, we must notify Congress prior to August 1, 2006 that the goal will not be implemented and provide our rationale for its removal.	Nov. 14, 2002 commitment letter from Sec. Thompson to Congress, goals I.A.3. and I.D.3.
August 2, 2006	FDA	Fees for FY 2007 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.	738(c)(5)
October 1, 2006 — User fee authority may be suspended for FY 2007 if appropriations for FY 2007 are less than an amount specified by the act. Section 738(g)(1)(D). **October 1, 2006 — Authority for third-party establishment inspections may be suspended for FY 2007 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).**			
October 26, 2006 (Four years)	GAO	GAO is to submit a report on the third-party inspection program, including a recommendation as to whether the program should be continued or terminated.	704(g)(12)
October 26, 2006 (Four years)	FDA [NIH]	FDA is to submit to congress a report concerning the adequacy of existing postmarket surveillance of 1) implanted devices used in children, and 2) devices used in pediatric populations. The report is to follow, and be based on, a study conducted by the Institute of Medicine under an agreement with FDA.	MDUFMA Sec. 212(c)
November 30, 2006	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (during FY 2006). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
December 31, 2006 (Annual Report for FY 2006)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
January 10, 2007	FDA	FDA must submit to Congress a study of — • The effect of medical device user fees on our ability fo conduct postmarket surveillance. • The extent to which device companies comply with postmarket surveillance requirements. • Any improvements needed for adequate postmarket surveillance, and the amount of funds needed to do so. • Recommendations as to whether, and in what amount, user fees should be used for postmarket surveillance, if fees are extended beyond FY 2007.	MDUFMA Sec. 104(b)
January 10, 2007	FDA	FDA must submit to Congress a study on our experience with third-party reviews of 510(k)s.	523(d).
January 31, 2007	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2006). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103

Date Due (Time beyond Effective Date)	**By**	**Requirement**	**Citation** (to FD&C Act, where possible)
[No date specified, but implicitly well in advance of October 1, 2007]	FDA	Public meeting to discuss FDA's proposed recommendations to Congress concerning goals and plans after FY 2007, and for reauthorization of the medical device user fee authority. FDA's proposed recommendations are to be published in the *Federal Register* prior to the public meeting.	MDUFMA Sec. 105(b)
October 1, 2007 — User fee authority expires. MDUFMA Sec. 107.			
October 1, 2007 — Authority for third-party review of 510(k)s expires. Section 523(c).			
October 1, 2007 — Authority for third-party establishment inspections may be suspended for FY 2008 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).			
November 30, 2007	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (through FY 2006). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec 103
December 31, 2007 (Annual Report for FY 2007)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
January 31, 2008	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2007). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec 103
January 31, 2008 — Section 103, and its requirement for annual reports to Congress, expires. MDUFMA Sec. 107.			
October 1, 2008 — Authority for third-party establishment inspections may be suspended for FY 2009 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).			
December 31, 2008 (Annual Report for FY 2008)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
October 1, 2009 — Authority for third-party establishment inspections may be suspended for FY 2010 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).			
December 31, 2009 (Annual Report for FY 2009)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
October 1, 2010 — Authority for third-party establishment inspections may be suspended for FY 2011 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).			
December 31, 2010 (Annual Report for FY 2010)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
October 1, 2011 — Authority for third-party establishment inspections may be suspended for FY 2012 if appropriations are less than an amount specified by the act. Section 704(g)(10)(A).			
December 31, 2011 (Annual Report for FY 2011)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	503(g)(4)(G)
October 1, 2012 — Third-party inspection authority expires. Section 704(g)(11).			

Notes:

Actions displayed in **bold font** are self-executing (these go into effect automatically). Actions displayed in *italic font* reflect dates that FDA has established by a regulation or *Federal Register* notice.

Key:	**Self-executing requirements set by law.**	*Dates set by regulation or notice.*

Some MDUFMA provisions remain in effect after October 1, 2012; the only such provision that includes a specific action date is the requirement for an annual report to Congress on the Office created to coordinate and monitor the review of combination products.

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The latest version of this document is available on the Internet at —

Text: www.fda.gov/cdrh/mdufma/actiondates1.html

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