Summary of the

# Medical Devices Technical Corrections Act (MDTCA)

November 2004

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## Summary

The Medical Devices Technical Corrections Act (MDTCA), P.L 108-214 amends and expands the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The President signed MDTCA into law on April 1, 2004.

MDTCA clarifies some potentially confusing language in MDUFMA, modifies important features of the provisions for third-party inspections, expands the provision for electronic labeling, delays the effective date of section 502(u) of the FD&C Act (this provision requires a device to "prominently and conspicuously" bear the name of its manufacturer; it was added by section 301of MDUFMA), and requires FDA to prepare and submit to Congress a report on barriers to the availability of devices intended for children.

The House Committee on Energy and Commerce prepared a report to accompany S. 1881, the bill that became MDTCA. The report provides a brief section-by-section analysis, and a very useful section that shows how MDTCA changes the text of the existing law. The report is available on FDA's Internet site —

Text format: www.fda.gov/cdrh/mdufma/hrpt108-433.html
PDF format: www.fda.gov/cdrh/mdufma/hrpt108-433.pdf

This summary provides a more detailed explanation of the changes made by MDTCA.

## Key Provisions

MDTCA makes important changes to MDUFMA in three areas:

- Changes to the third-party inspection program.
- Expansion of the provision for electronic labeling.
- Delays the effective date of new section 502(u) of the FD&C Act until October 26, 2005 (36 months after enactment of MDUFMA, and 18 months beyond the original effective date set by MDUFMA).

**Changes to the Third-Party Inspection Program**.

MDTCA removes significant obstacles to the use of third-party inspections, provides greater flexibility in how third-party inspections may be performed and completed, and strengthens FDA's ability to ensure accredited persons and the establishments they inspect remain in full compliance with statutory requirements.

*Simplified requirements remove obstacles to the use of third-party inspections*. MDTCA reduces the burdens that must be met for an establishment to obtain a third-party inspection. Section 2(b)(1)(C)(iii)(I) changes the requirement concerning foreign recognition of inspections conducted by FDA-accredited persons or FDA itself. MDUFMA required a showing that the foreign government would recognize *both* an inspection by an accredited person, *and* an inspection by FDA. This requirement can now be met when *either* ("1 or both") of these conditions is met. Similarly, section 2(b)(1)(C)(iii)(III) now permits inspection by an accredited person when a foreign country recognizes an inspection by *either* FDA *or* by an accredited person. Previously, the use of a third-party was conditioned on foreign recognition of inspections conducted by FDA.

*Greater flexibility in performing and completing third-party inspections*. Section 2(b)(1)(C)(ii)(I) changes third-party inspection eligibility conditions to permit an inspection by an accredited person to be completed during a *two-year period*. This change will permit an establishment to schedule a complete inspection in phases, and to coordinate those phases with other objectives, such as obtaining ISO certification. It also permits an accredited person to send specialized personnel at different times to complete an inspection. All of FDA's inspectional requirements must be met within the two-year period.

Section 2(b)(1)(C)(iv)(I) changes the requirement concerning periodic FDA inspection of establishments that use third-party inspections. The change limits the use of third-party inspections to a *four-year period* rather than a limit of *two consecutive inspections*. This reflects MDTCA's shift to permit an inspection by an accredited person to be completed in stages during a two-year period. Because a complete third-party inspection must be completed within two years, FDA expects two complete third-party inspections during the four-year period provided by this section.

*Strengthening of FDA's ability to ensure compliance with statutory requirements*. Section 2(b)(1)(B) clarifies that if FDA determines that a person accredited to conduct third-party inspections has a financial conflict of interest with the owner or operator of an establishment inspected by the accredited person, FDA may withdraw that person's accreditation. Section 2(b)(1)(E) provides FDA clear authority to suspend an establishment's eligibility to use third-party inspections if FDA finds the establishment is substantially not in compliance with statutory requirements.

**Expanded Authority for Electronic Labeling**

Section 2(b)(2)(B)(i) extends the electronic labeling provision (section 502(f) of the FD&C Act) to —

- Prescription devices used by a health care professional, regardless of the setting in which the device is used. MDUMFA authorized electronic labeling only when the prescription device is used in a health care facility.
- *In vitro* diagnostic devices used by a health care professional, regardless of the setting in which the device is used. This clarification removes any doubt as to whether *in vitro* diagnostic devices qualify for electronic labeling.

- *In vitro* diagnostic devices used in blood establishments. MDUMFA authorized electronic labeling only when the device is used in a health care facility; this change recognizes that *in vitro* diagnostic devices are essential to blood establishments and extends the benefits of electronic labeling to those establishments.

These changes significantly extend the circumstances in which electronic labeling may be used. The following table summarizes the law as it now stands.

**When May Electronic Labeling Be Used?**

| Setting Where Device is Intended to be Used | Prescription Devices | | *In Vitro* Diagnostic Devices | |
|---|---|---|---|---|
| | Intended to be Used by a Health Care Professional | All Other Users | Intended to be Used by a Health Care Professional | All Other Users |
| Health Care Facility | ✓ | ✓ | ✓ | ✗[1] |
| Blood Establishment | ✓ | ✗ | ✓ | ✓ |
| All Other Settings | ✓ | ✗ | ✓ | ✗ |

✓ = Permitted ✗ = Not Permitted

[1] If the *in vitro* diagnostic device is *also* a prescription device intended to be used in a health care facility, electronic labeling may be used.

**Delay in the Effective Date of Section 502(u) of the FD&C Act**

Section 2(c)(1) delays the effective date of new section 502(u) of the FD&C Act (added by section 301 of MDUFMA) until October 26, 2005 (36 months after enactment of MDUFMA, and 18 months beyond the original effective date set by MDUFMA). When it goes into effect, section 502(u) will require a device to "prominently and conspicuously" bear the name of its manufacturer. This can be in the form of a "generally recognized" abbreviation or a unique and "generally recognized" symbol. FDA may waive this requirement if it is "not feasible for the device or would compromise . . . the safety or effectiveness of the device."

This change gives FDA and industry more time to determine how best to implement section 502(u), but the task is still considered very challenging. On June 23, 2003, FDA issued draft guidance to advise that we do not intend to object if a manufacturer does not fully implement the changes required by section 502(u) for a period of up to 18 months after FDA issues final guidance on our interpretation and implementation of section 502(u). FDA is currently examining the possibility of providing categorical waivers for devices that meet either of the statutory criteria for obtaining a waiver under section 502(u): when it can be shown that the labeling requirement "is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device." FDA expects to publish final guidance in 2004, explaining how to obtain individual waivers and how to comply with the new labeling requirements; this guidance will reflect MDTCA's extension of the effective date of this provision.

**Additional Changes**

MDTCA makes many other technical corrections and clarifications, mostly minor. These are explained in the section-by-section analysis.

## Section-by-Section Analysis

The following summary provides a brief overview of FDA's general interpretation of the effects of each provision of MDTCA. Particularly significant changes are indicated by a star (★).

| MDTCA Section | Explanation |
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| **Short Title** | |
| 1 | Designates the act as the Medical Devices Technical Corrections Act. |
| **Changes Relating to Medical Device User Fees** | |
| 2(a)(1)(A) | Narrows the definition of *panel-track supplement* provided by MDUFMA to help distinguish between panel-track supplements and 180-day supplements. A PMA supplement is now considered a panel-track supplement only if "substantial" clinical data "are necessary" to provide reasonable assurance of the safety and effectiveness of the device. |
| 2(a)(1)(B) | Changes the definition of *real-time supplement* to match prior FDA policy by excluding the review of proposed manufacturing changes through this type of PMA supplement. |
| 2(a)(1)(C) | Extends the definition of the *process for the review of device applications* to include evaluation of postmarket studies required as a condition of approval of a premarket report. This allows MDUFMA fees to be applied to this activity. |
| 2(a)(1)(D) | Clarifies that the term *affiliate* can include an international (*i.e.*, foreign) business entity. FDA was already interpreting the term in this manner. |
| 2(a)(2)(A)(i)(I) | Clarifies that 510(k) fees are subject to small business reductions under section 738(e). FDA was already interpreting the provision in this manner. |
| 2(a)(2)(A)(i)(II) | Clarifies how fees for 180-day supplements are to be determined each year (eliminates erroneous reference to compensating adjustment). |
| 2(a)(2)(A)(i)(III) | Clarifies how fees for 510(k) submissions are to be determined each year (eliminates erroneous reference to compensating adjustment). |

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| 2(a)(2)(A)(ii) | Clarifies that all refund provisions of section 738(a)(1)(D) apply to premarket reports. |
| 2(a)(2)(B) | Corrects punctuation. |
| 2(a)(2)(C)(i)<br>*and*<br>2(a)(2)(C)(ii)(II) | ★ Correction to reflect Congressional intent that reduced small business fees for 510(k)s do not go into effect until FY 2004. FDA had interpreted the statute in this manner, and did not offer a reduced small business fee for 510(k)s submitted during FY 2003. |
| 2(a)(2)(C)(ii)(I) | Corrects punctuation. |
| 2(a)(2)(D) | Removes reference to *filing* (FDA does not file 510(k)s). |
| 2(a)(2)(E)(i) and 2(a)(2)(E)(ii) | Revises subclause numbering to conform with standard method. |
| 2(a)(2)(E)(iii) | Provides subclause title ("IN GENERAL.") |
| 2(a)(2)(E)(iv) | Clarifies Congressional intent by explicitly stating that MDUFMA user fees may not be collected in any fiscal year where actual appropriations for the process for the review of device applications are more than 5% below the appropriations amount required by MDUFMA. |
| **Changes Relating to Third-Party Inspections** | |
| 2(b)(1)(A) | Corrects grammar (improves confusing sentence structure). |
| 2(b)(1)(B) | ★ Clarifies Congressional intent by explicitly providing that if FDA determines that a person accredited to conduct third-party inspections has a financial conflict of interest with the owner or operator of an establishment inspected by the accredited person, FDA may withdraw that person's accreditation. |
| 2(b)(1)(C)(i) | Simplifies sentence structure by using a reference to another section rather than repeating criteria. |
| 2(b)(1)(C)(ii)(I) | ★ Changes third-party inspection eligibility conditions to permit an inspection by an accredited person to be completed in stages during a two-year period. |
| 2(b)(1)(C)(ii)(II) | Clarifies that the person referred to is an *accredited person*. |

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| 2(b)(1)(C)(iii)(I) | ★ Changes the requirement concerning foreign recognition of inspections conducted by FDA-accredited persons or FDA itself. MDUFMA required a showing that *both* —<br>• the foreign government would recognize an inspection by an accredited person, *and*<br>• the law of the foreign government would recognize an inspection by FDA.<br>This requirement can now be met when *either* ("1 or both") of these conditions is met. |
| 2(b)(1)(C)(iii)(II) | Clarifies that foreign certification, accreditation, or recognition of an accredited person means recognition that the accredited person is authorized to conduct establishment inspections (as opposed to recognition for some other purpose). Also reflects revised section numbering. |
| 2(b)(1)(C)(iii)(III) | ★ Permits inspection by an accredited person when law of a foreign country recognizes an inspection by FDA *or* by an accredited person. Previously, the use of a third-party was conditioned on foreign recognition of inspections conducted by FDA. |
| 2(b)(1)(C)(iv)(I) | ★ Changes the requirement concerning periodic FDA inspection of establishments that use third-party inspections. The change limits the use of third-party inspections to a *four-year period* rather than a limit of *two consecutive inspections*. This reflects MDTCA's shift to permit an inspection by an accredited person to be completed in stages over a two-year period. Because a complete third-party inspection must be completed within two years, FDA expects two complete third-party inspections during the four-year period provided by this section. |
| 2(b)(1)(C)(iv)(II) | (aa) deletes a redundant requirement (the requirement also appears earlier in the section). (bb) corrects a typographical omission to reflect the actual intent of the provision. |
| 2(b)(1)(C)(iv)(III) | Minor clarification of intent; makes clear that once a waiver has been granted or deemed granted (permitting an additional use of an accredited person to provide an inspection beyond the normal limit of two complete inspections in a four-year period), no additional waiver is possible until FDA has inspected the establishment. |
| 2(b)(1)(C)(v) | Minor clarification of intent. Specifies the establishments to which the provision applies. |
| 2(b)(1)(D)(i) | Minor clarification of intent. FDA may request that an establishment provide data describing compliance with any applicable provisions of the FD&C Act (not just sections 501 and 502). |
| 2(b)(1)(D)(ii)(I) | Minor clarification of intent. Changes term to conform with standard FDA usage. |

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| 2(b)(1)(D)(ii)(II) | Minor clarification of intent. FDA will request only relevant compliance data. |
| 2(b)(1)(E) | ★ Provides explicit authority for FDA to suspend an establishment's eligibility to use third-party inspections if FDA finds the establishment is substantially not in compliance with statutory requirements. |
| 2(b)(1)(F) | Clarifies intent by simplifying language. |
| 2(b)(1)(G) | Corrects wording. |
| 2(b)(1)(H)(i) | Clarifies the information GAO is to include in its report to Congress (due October 26, 2006). GAO must report the number of Quality Systems / GMP inspections conducted by FDA, and the number of such inspections conducted by accredited persons. |
| 2(b)(1)(H)(ii) | Clarifies the information GAO is to include in its report to Congress (due October 26, 2006). GAO is to determine whether the quality of data obtained from inspections performed by accredited persons is comparable to that obtained from inspections conducted by FDA. |
| 2(b)(2)(A) | Clarifies intent by simplifying language. |
| **Changes Relating to Electronic Labeling** | |
| 2(b)(2)(B)(i) | ★ Extends electronic labeling provision (section 502(f) of the FD&C Act) to —<br>• prescription devices used by a health care professional, regardless of setting (use no longer needs to be in a health care facility);<br>• *in vitro diagnostic* devices used by a health care professional, regardless of setting, and<br>• *in vitro diagnostic* devices used in blood establishments. |
| 2(b)(2)(B)(ii) and (iii) | Corrects punctuation. |
| 2(b)(2)(B)(iv) and (v) | Minor clarification of intent; makes language consistent with extension of electronic labeling to additional settings and devices. |
| **Change in Effective Date of Section 502(u) of the FD&C Act** | |
| 2(c)(1) | ★ Delays the effective date of section 502(u) of the FD&C Act (added by section 301 of MDUFMA) until October 26, 2005 (36 months after enactment of MDUFMA, and 18 months beyond the original effective date set by MDUFMA). This provision will require a device to "prominently and conspicuously" bear the name of its manufacturer. |
| **Other Minor Clarifications and Corrections** | |
| 2(c)(2)(A) and (B)(i) | Clarifies intent by correcting sentence structure. |

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| 2(c)(2)(B)(ii) | Corrects spelling (*semi-critical* is standard form used by other sections of MDUFMA). |
| 2(d)(1)(A)(i) | Renumbers one of two provisions that MDUFMA designated as section 515(c)(3). See MDUFMA sections 209 and 302(c)(2)(A). |
| 2(d)(1)(A)(ii) | Following submission of a complete PMA, restricts further FDA review of a PMA module that FDA previously reviewed and found acceptable to instances where there is a *significant* issue of safety or effectiveness. |
| 2(d)(1)(B) | Modifies language to reflect that the paragraph referred to was redesignated by MDUFMA. |
| 2(d)(2)(A) | Provides subclause title ("IN GENERAL."), changes subclause numbering, and makes minor changes to language to reflect renumbering. |
| 2(d)(2)(B) and (C) | Revises subsection references to reflect renumbering of provisions within section 738(a) of the FD&C Act. |
| 2(d)(3)(A) | Corrects U.S. Code citation. |
| 2(d)(3)(B)(i) | Deletes unnecessary definitions (the definitions provided in section 737 of the FD&C Act apply without need for repetition). |
| 2(d)(3)(B)(ii) | Revises subclause numbering to conform with standard method. |
| 2(d)(3)(B)(iii) | Revises subsection structure and numbering to reflect deletion of paragraph providing unnecessary definitions, leaving only one paragraph. |
| 2(d)(3)(C) | Deletes reference to "phase IV trials" (Medical device postmarketing trials are not usually referred to as phase IV trials.) |
| **Report to Congress on Barriers to Availability of Devices Intended for Children** | |
| 3 | ★ Requires FDA to submit a report to Congress on the barriers to availability of devices intended for the diagnosis or treatment of diseases and conditions that affect children. The report is due September 28, 2004 (180 days after enactment of MDTCA). |

## Full Text of MDUFMA and MDTCA

FDA's Internet site provides the full text of both MDUFMA and MDTCA:

MDUFMA —
Text format: www.fda.gov/cdrh/mdufma/mdufma2002.html
PDF format: www.fda.gov/cdrh/mdufma/mdufma2002.pdf

MDTCA —

Text format: www.fda.gov/cdrh/mdufma/mdtca.html
PDF format: www.fda.gov/cdrh/mdufma/mdtca.pdf

## Additional Information on MDUFMA

FDA Internet sites provides a wide variety of additional information on MDUFMA —

- www.fda.gov/cdrh/mdufma — general information, including current user fees, links to guidance documents, *Federal Register* notices, and the latest news and announcements from FDA.

- www.fda.gov/cber/mdufma/mdufma.htm — information focusing on biologics.