Summary of the
Medical Device User Fee and Modernization Act of 2002

Including Changes Made by the
Medical Devices Technical Corrections Act (April 1, 2004)

November 2004

Center for Devices and Radiological Health

Contents

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Text: www.fda.gov/cdrh/mdufma/mdufmasummary.html
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BACKGROUND

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L 107-250, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide FDA new responsibilities, resources, and challenges. MDUFMA was signed into law October 26, 2002.

On April 1, 2004, the Medical Devices Technical Corrections Act (MDTCA), P.L. 108-214, was signed into law; MDTCA amends MDUFMA to clarify Congress's intent and to improve and expand upon some features of MDUFMA. FDA's Internet site provides the full text of both MDUFMA and MDTCA; we also provide a detailed summary of the changes made by MDTCA:

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

MDTCA (official text) —
Text format: www.fda.gov/cdrh/mdufma/mdtca.html
PDF format: www.fda.gov/cdrh/mdufma/mdtca.pdf

Summary of changes made by MDTCA (FDA document) —
Text format: www.fda.gov/cdrh/mdufma/mdtcasummary.html
PDF format: www.fda.gov/cdrh/mdufma/mdtcasummary.pdf

Wherever possible, this summary provides citations to sections of the Food, Drug, and Cosmetic Act (referred to as the "FD&C Act"), as amended by MDUFMA and MDTCA. Except where otherwise stated —

- References to MDUFMA mean MDUFMA as amended by MDTCA.
- Citations to §§ 101 – 303 that are not otherwise identified refer to MDUFMA.
- References to "the act" mean the Federal Food, Drug, and Cosmetic Act, as amended by MDUFMA and MDTCA.
- To help distinguish references to the FD&C Act from other citations, the word "section" is used for citations to the FD&C Act (*e.g.*, "section 502(u)" refers to the FD&C Act), and a section symbol (§) is used for all other citations (*e.g.*, "§ 301(a)" of MDUFMA).

FDA MDUFMA Guidance. In some instances, FDA has developed guidance that explains how we are interpreting and applying a particular MDUFMA provision or program. This summary includes references to FDA guidance only when the guidance is essential to a basic understanding of a statutory provision or when the guidance fulfills a statutory requirement. FDA provides a complete list of all MDUFMA guidance documents on our Internet site, with links to the documents in text and PDF formats; see www.fda.gov/cdrh/mdufma/guidance.

Key Features of MDUFMA. MDUFMA has four particularly significant features:

- *User fees for premarket reviews* of PMAs, PDPs, premarket reports (a new category of premarket application for reprocessed single-use devices), BLAs, certain supplements, and 510(k)s.
- *Performance goals* for many types of premarket reviews. These goals become more demanding over time, and include FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to our final action on a submission).
- *Establishment inspections may be conducted by accredited persons* (third-parties), under carefully prescribed conditions.
- *New regulatory requirements for reprocessed single-use devices*, including a new category of premarket submission, the premarket report.

The user fees authorized by MDUFMA are intended to add $25.1 million to FDA's medical device budget authority during FY 2003, rising each year until fees amount to $35 million in FY 2007. These sums are protected from inflation and changes in workload and other factors through a set of adjustments. The revenues from these fees, and from additional appropriations, will allow FDA to pursue a set of ambitious performance goals; these goals are summarized in DHHS Secretary Thompson's November 14, 2002 letter to Congress (referred to as the "FDA commitment letter") and are incorporated by reference in MDUFMA; see section 101(3) of MDUFMA (this provision is not codified in the FD&C Act) and sections 738(g)(1)(A)-(D) of the FD&C Act. The payment of a premarket review fee is not linked in any way to FDA's final decision on a submission.

Use of Resources. In enacting MDUFMA, Congress recognized that "the public health will be served" by providing additional funds to FDA for "the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met." The additional resources are to be "dedicated to meeting the goals identified in the letters from the Secretary" to House and Senate committees. See § 101of MDUFMA.

How Are MDUFMA's Authorized Fee Amounts Adjusted?

Section 738(c) of the FD&C Act requires MDUFMA fee revenue targets to be adjusted each year to account for —

- Inflation and pay raises (referred to as the "inflation adjustment").
- Increased workload throughout the "process for the review of device applications" (the "workload adjustment").
- Shortfalls in revenue below the previous year's adjusted revenue target (the "compensating adjustment").
- Any legislation requiring DHHS to fund additional employee retirement costs.
- For FY 2007 only, a special adjustment may be required to provide for an orderly sunset of the MDUFMA fee program (the "final year adjustment"). If FDA has sufficient carryover reserves from fees to fund the process for the review of device applications during the first three months of FY 2008, this adjustment will not be required.

Total User Fee Amounts Authorized by MDUFMA

Year	Authorized Fee Amounts		Actual Receipts
	FY 2003 Dollars[1]	Adjusted[2]	
FY 2003	$25,125,000	$25,125,000[3]	$21,889,582
FY 2004	$27,255,000	$33,896,789[4]	$26,832,000[6]
FY 2005	$29,785,000	$32,429,908[5]	To be determined
FY 2006	$32,615,000	To be determined	To be determined
FY 2007	$35,000,000	To be determined	To be determined

[1] See section 738(b).

[2] This is the amount FDA is actually authorized to collect from fees. See section 738(c).

[3] No adjustment, as FY 2003 was the first year of the program.

[4] The Adjusted amount for FY 2004 includes a mandatory increase to account for inflation and a compensating adjustment of $5,478,000. The compensating adjustment was the projected deficit in FY 2003 user fee receipts at the time FDA set the fee rates for FY 2004. After the close of FY 2003, FDA determined that the actual deficit in FY 2003 fee receipts was $3,235,418.

[5] The Adjusted amount shown for FY 2005 includes a mandatory increase to account for inflation No compensating adjustment was included in the Adjusted amount for FY 2005.

[6] Preliminary estimate.

These user fee amounts are in addition to the amounts appropriated by Congress for FDA's medical device program. Total program resources for FY 2003 through FY 2005 are shown in the following table.

Total Medical Device Program Resources			
Source	FY 2003 (Actual)	FY 2004 (Actual)	FY 2005 (Anticipated)
MDUFMA Review Fees	$21,889,582	$26,832,000[1]	$32,429,908[2]
Appropriations	$193,455,000	$191,144,000	$216,699,000[3]
Total	$215,346,585	$217,976,000[1]	$249,130,913

[1] Preliminary estimate.

[2] See FDA's *Federal Register* notice setting review fees for FY 2005, 69 F.R. 46153, August 2, 2004.

[3] President's Budget Request for FY 2005.

For FY 2005, MDUFMA review fees will provide 13.0% of FDA's total anticipated medical device program resources.

Additional Provisions. Additional provisions added by MDUFMA include:

- The third-party 510(k) review program is continued through FY 2006.
- The review of combination products will be coordinated by a new office in the Office of the Commissioner. (FDA established the Office of Combination Products to undertake this responsibility; see www.fda.gov/oc/combination for additional information about the office and its activities.)
- Electronic labeling is authorized for prescription devices intended for use in health care facilities, *in vitro* diagnostic devices intended for use in blood establishments, and prescription and *in vitro* diagnostic devices intended for use in any setting by a health care profession.
- FDA may require electronic registration of device establishments, when feasible.
- Section 513(i)(1)(E) of the act (determination of intended use to be based on proposed labeling submitted in a 510(k) premarket notification) is made permanent by revoking a sunset provision.
- The law now explicitly provides for modular review of PMAs.
- New provisions are added concerning devices intended for pediatric use.
- The manufacturer of a device must be identified on the device itself, with certain exceptions. This provision goes into effect October 26, 2005.
- The U.S. Government Accountability Office (GAO) and the National Institutes of Health (NIH) are directed to prepare reports concerning breast implants.
- If appropriations for the medical device program do not reach specified levels, GAO is directed to conduct periodic audits relating to FDA performance.
- MDUFMA authorizes additional appropriations for postmarket surveillance — $3 million for FY 2003, $6 million for FY 2004, and "such sums as may be necessary" in subsequent years.

MEDICAL DEVICE REVIEW FEES

Purpose. Section 738 of the FD&C Act (added by § 102 of MDUFMA) authorizes FDA to assess fees for the premarket review of —

- PMAs, PDPs, premarket reports (a new form of premarket application for a reprocessed single-use device), panel-track supplements, 180-day supplements, and real-time supplements,
- BLAs and efficacy supplements, and
- 510(k)s.

Applications received on or after October 1, 2002 are subject to a fee. § 106.

Fee revenues will support the "process for the review of device applications," section 737(5), which includes —

- premarket reviews,
- premarket inspections,
- monitoring of research relating to premarket reviews,
- review of INDs and IDEs,
- monitoring of research conducted to develop INDs or IDEs,
- development of guidance, policy documents, and regulations to improve the process for the review of device applications,
- development of test methods and standards applicable to premarket reviews,
- technical assistance to applicants,
- initial classification or reclassification of a device,
- actions required to call for PMAs for pre-Amendments class III devices,
- evaluation of postmarket studies required as a condition of approval,
- compiling, developing, and reviewing information concerning devices subject to premarket review to identify safety and effectiveness issues.

Payment of fees. Fees are due when the premarket submission is made to FDA. In the case of a modular PMA, the entire fee is due with the first module submitted to FDA. Section 738(a)(1)(C). FDA will not accept a submission for review until the entire fee due is paid.

Small business fees and waivers. In order to avoid creating governmental barriers to entry into the device marketplace, the MDUFMA user fee program contains a provision to protect small businesses. If you qualify as a small business, you may pay reduced user fees and may obtain a one-time waiver of the fee for your first premarket application.

Qualification as a small business. To qualify as a small business under MDUFMA, your gross receipts or sales, including that of all of your affiliates, partners, and parent firms, cannot exceed $30 million (this is the threshold for FY 2005; each year, FDA issues new guidance

that explains how to qualify as a small business, including the qualification threshold amount). Sections 738(d)(2)(A)(i) and 738(e)(2)(A). An applicant must pay the standard fee unless it demonstrates it is a small business by submitting a copy of its most-recent Federal income tax return (and returns of all affiliates, partners, and parent firms). Sections 738(d)(2)(B) and 738(e)(2)(B). FDA's decision as to whether an applicant qualifies as a small business is not reviewable. Sections 738(d)(2)(D) and 738(e)(2)(D). For additional information on the information you need to provide to qualify as a small business, see FDA's guidance —

FY 2005 MDUFMA Small Business Qualification Worksheet and Certification —
Text format: www.fda.gov/cdrh/mdufma/guidance/2005.html
PDF format: www.fda.gov/cdrh/mdufma/guidance/2005.pdf

Adjustment of the small business threshold. Each year, FDA can adjust the small business threshold to reflect actual experience; the threshold is to be set to reduce fee revenues 16% below the level that would be received if there were no small business exception. Section 738(d)(2)(A)(ii). For example, if the current threshold ($30 million) results in the loss of too much revenue, FDA may reduce the threshold in the future to a level that will result in a revenue stream that better meets the expectations and intent of Congress.

MDUFMA Fee Structure		
Application	**Standard Fee Structure**[1] (Percent of Base Fee)	**Small Business Fee** (Percent of Standard Fee)
Premarket application (PMA, PDP, BLA)	Base Fee[2]	38%
Premarket report[3]	100%	38%
Panel-track PMA supplement	100%	38%
BLA efficacy supplement	100%	38%
180-day PMA supplement	21.5%	38%
Real-time PMA supplement	7.2%	38%
510(k)	1.42%	80%

[1] Section 738(a)(1)(A).

[2] All other fees are a specified percentage of this fee. Section 738(c)(5).

[3] A premarket report is essentially a PMA for a class III device that is a reprocessed single-use device. See section 515(c)(2)(A).

Current Review Fees. FDA announced the MDUFMA review fees for FY 2005 in the *Federal Register* of August 2, 2004; see 69 F.R. 46153. FY 2005 fees apply to applications received from October 1, 2004 through September 30, 2005. FDA must receive *both* the application *and* the *entire amount* of the fee due for that application by September 30, 2005 or the fee due will be the fee in effect for the next fiscal year, FY 2006 (FDA will announce the fee rates for FY 2006 by August 2, 2005). The following tables show the fees in effect for FY 2005 and fee exemptions and waivers that are available.

MDUFMA Review Fees for FY 2005		
	Fees for FY 2005	
Application	Standard Fee	Small Business
Premarket application (PMA, PDP, BLA)	$239,237	$90,910
Premarket report	$239,237	$90,910
Panel-track PMA supplement	$239,237	$90,910
BLA efficacy supplement	$239,237	$90,910
180-day PMA supplement	$51,436	$19,546
Real-time PMA supplement	$17,225	$6,546
510(k) premarket notification	$3,502	$2,802

Fee Exemptions and Waivers	
Category	Exemption or Waiver
HDE	Exempt from any fee. Section 738(a)(1)(B)(i).
BLA for a product licensed for further manufacturing use only	Exempt from any fee. Section 738(a)(1)(B)(ii).
First PMA, PDP, BLA, or premarket report from a small business	One-time waiver of the fee that would otherwise apply. Section 738(d)(1).
First premarket report submitted by a person who submitted a premarket application for the same device (the reprocessed device) prior to October 1, 2002.	One-time waiver of the fee that would otherwise apply. See section 102(b) of MDUFMA (this waiver is not codified as part of the FD&C Act). This provision is intended to avoid penalizing companies that previously submitted a PMA for a reprocessed device, but who must submit a new application to satisfy the requirements added by MDUFMA.
Third-party 510(k)	Exempt from any FDA fee; however, the third-party may charge a fee for its review. Section 738(a)(1)(B)(iv).
Any application for a device intended *solely* for pediatric use.	Exempt from any fee. If an applicant obtains an exemption under this provision, and later submits a supplement for adult use, that supplement is subject to the fee then in effect for an original premarket application. Section 738(a)(1)(B)(v).
Any application from a State or Federal Government entity.	Exempt from any fee *unless* the device is to be distributed commercially. Section 738(a)(1)(B)(iii).

Failure to pay a fee. If a fee is not paid, the submission "shall be considered incomplete and shall not be accepted for filing" until the fee is paid in full. Section 738(f). If a fee is not paid within 30 days after it is due, the fee may be treated as a claim of the U.S. Government. Section 738(i).

Refunds. Under some conditions, FDA will make a partial refund of a fee paid for review of a premarket application, premarket report, or supplement.

Upon written request made within 180 days after the fee is due, Section 738(j), FDA will refund 75% of a fee if we refuse to file a submission, or if the applicant withdraws a submission prior to our filing decision. Section 738(a)(1)(D)(i) and (ii). If an applicant withdraws a premarket application, premarket report, or supplement *after* filing, but *before* a first action, FDA *may*, but is not required to, refund any portion of the fee, based on the level of effort already expended; FDA's decision to make or refuse a refund after filing, and our determination of the amount of any refund, is not reviewable. Section 738(a)(1)(D)(iii). FDA cannot make any refund after we have taken a first action on a submission (our "first action" can be any of the following actions: major deficiency, not approvable, approvable, approvable pending GMP inspection, denial, and approval). Once a 510(k) has been received and the fee has been paid, FDA cannot make any refund of any portion of the fee. FDA guidance documents provide additional detail on FDA's implementation of MDUFMA's refund provisions. See —

- *User Fees and Refunds for Premarket Notification Submissions (510(k)s)*
  Text format: www.fda.gov/cdrh/mdufma/guidance/1511.html
  PDF format: www.fda.gov/cdrh/mdufma/guidance/1511.pdf

- *User Fees and Refunds for Premarket Approval Applications*
  Text format: www.fda.gov/cdrh/mdufma/guidance/1224.html
  PDF format: www.fda.gov/cdrh/mdufma/guidance/1224.pdf

- *Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA*
  Text format: www.fda.gov/cdrh/mdufma/guidance/1303.html
  PDF format: www.fda.gov/cdrh/mdufma/guidance/1303.pdf

The following table summarizes the primary circumstances where FDA may make a partial refund of a MDUFMA user fee and the portion of the fee we will refund.

When May FDA Make a Partial Refund of a MDUFMA Review Fee?		
	Type of Submission	
Circumstance that Determines the Amount of a Refund	Premarket Application, Premarket Report, Supplement	510(k)
Applicant withdraws the submission prior to FDA filing decision	✓ (FDA will refund 75% of the fee)	✗
FDA refuses to file	✓ (FDA will refund 75% of the fee)	✗
Applicant withdraws *after* filing, but *before* an FDA first action	✓ (FDA *may*, at our discretion, refund a portion of the fee)	✗
Applicant withdraws *after* an FDA first action	✗	✗

✓ = Refund may be available ✗ = No refund will be made

Refund for certain unnecessary 510(k) submissions. FDA will automatically refund any fee paid for a 510(k) review if we determine that the product is not a device or if we determine the device is exempt from 510(k) premarket notification under our classification regulations.

Publication of fees. By August 2 of each year, FDA will announce new MDUFMA user fees in the *Federal Register* (60 days before the start of the upcoming fiscal year). The new fees go into effect October 1 (the fiscal year runs from October 1 to September 30).

Performance goals. Under section 738(g), FDA is expected to meet performance goals defined in a letter from DHHS Secretary Thompson to Congress. This letter, generally referred to as the "FDA commitment letter," was published in the *Congressional Record* (November 19, 2002, page S11549), and is available on FDA's MDUFMA Internet site.

Few goals apply during FY 2003 and FY 2004, allowing FDA time to hire staff, build infrastructure, provide guidance to industry, and take other actions to implement the new law. More goals go into effect each year from FY 2005 through FY 2007, and the goals become more demanding each year.

In a fiscal year where appropriations for salaries and expenses for devices and radiological health do not meet certain levels, FDA is "expected to meet such goals to the extent practicable, taking into account the amounts that are available . . . for such purpose." Section 738(g)(1)(A)(ii)(I). For fiscal years 2006 and 2007, if appropriations for that year do not meet certain levels, FDA may not assess medical device user fees for that year and FDA is not expected to meet any performance goals for that year. Section 738(g)(1)(C) and (D).

FDA Performance Goals
Under the Medical Device User Fee and Modernization Act of 2002

(Extract from November 14, 2002 FDA Commitment Letter from DHHS Secretary Thompson to Congress, Section I, Paragraphs A through H.[1])

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal) 2003	2004	2005	2006	2007
PMAs, Panel-Track Supplements, Premarket Reports						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	—	—	—	80%	90%
• FDA decision – median performance	180 days	—	—	—	—	50%†
• First action – "major deficiency" letter	150 days	—	—	75%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	—	75%	80%	90%
• Second or later action – "major deficiency" letter	120 days	—	—	75%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	—	—	75%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%

[1] This table summarizes all MDUFMA performance goals that have objective review time standards and quantifiable measures of performance. Additional commitments that must be evaluated through descriptive measures are found in section I, paragraphs I through P of FDA's November 14, 2002 commitment letter.

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal) 2003	2004	2005	2006	2007
Expedited PMAs These goals apply when FDA has granted expedited status; the applicant has attended a pre-filing meeting; manufacturing facilities are ready for inspection; and the PMA is substantively complete as defined at the pre-filing meeting.						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	—	—	70%	80%	90%
• First action – "major deficiency" letter	120 days	—	—	70%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	—	—	70%	80%	90%
• Second or later action – "major deficiency" letter	100 days	—	—	70%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	—	—	70%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%
180-day PMA Supplements						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	—	80%	80%	90%
• First action – "not approvable" letter	120 days	—	—	80%	85%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	—	80%	85%	90%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	—	—	80%	85%	90%
510(k)s						
• FDA decision (SE/NSE)	90 days	—	—	75%	75%	80%†
• First action – "additional information" letter	75 days	—	—	70%	80%	90%
• Second or later action	60 days	—	—	70%	80%	90%

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal) 2003	2004	2005	2006	2007
Biologics Licensing Applications - BLAs						
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	—	—	—	75%	90%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	—	—	—	75%	90%
BLA Supplements						
• Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10.0 months	—	—	—	75%	90%
• Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6.0 months	—	—	—	75%	90%
• Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4.0 months	—	—	—	75%	90%
BLA Resubmissions, BLA Supplement Resubmissions						
• Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	2.0 months	—	—	75%	80%	90%
• Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	6.0 months	—	—	75%	80%	90%

† This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether the goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal. If the goal is removed, the goals in effect for FY 2006 will remain in effect.

Definitions for the terms used here are provided in Section III of the FDA commitment letter.

Additional goal commitments. In addition to the detailed quantitative performance goals outlined above, the FDA commitment letter provides several other important goals that do not have specific time frames or direct measures of our performance; these goals are found in Section I, Paragraphs I through P of the FDA commitment letter —

- FDA and industry agree that informal and formal meetings (*e.g.*, determination and agreement meetings, informal pre-IDE meetings, pre-PMA meetings, pre-PMA filing meetings) are critical to ensure high application quality and achievement of the detailed performance goals set for the device review program. FDA will work to expand the use of productive meetings with industry.
- FDA will maintain current (pre-MDUFMA) performance in review areas where specific performance goals have not been identified.
- FDA will apply significant user fee revenues to support reviewer training, hiring of additional reviewers, and expanded outside contracting to achieve the identified performance goals in a responsible and efficient manner.
- FDA will issue guidance on PMA modular review under new section 515(c)(3) of the Federal Food, Drug, and Cosmetic Act. (FDA has issued this guidance; see Modular Review, below.) FDA will also work with stakeholders to develop performance goals for this program. Until specific performance goals are developed, FDA will complete our review of individual modules in as little time as is reasonably possible.
- FDA's Center for Biologics Evaluation and Research will, if feasible, identify a category of "follow-on" licensed devices and collect information to determine whether alternative performance goals for such a category are appropriate.
- FDA will consult with stakeholders concerning the bundling of multiple related submissions. After such consultation, the Agency will either issue guidance on bundling or publish a notice explaining why it has determined that bundling is inappropriate. FDA met this goal by consulting with stakeholders and issuing a guidance document; see —
    - *Bundling Multiple Devices or Multiple Indications in a Single Submission*
      Text format: www.fda.gov/cdrh/mdufma/guidance/1215.html
      PDF format: www.fda.gov/cdrh/mdufma/guidance/1215.pdf
- FDA will continue its efforts toward development of electronic receipt and review of applications. The FDA commitment letter notes that the MDUFMA user fee program will not produce sufficient resources to ensure completion of this effort.
- FDA will work to improve the scheduling and timeliness of preapproval inspections and will report our progress in the annual performance report to Congress.

Oversight of MDUFMA Review Fee Provisions. MDUFMA provides for several oversight mechanisms —

- *Annual stakeholders' meeting*. As provided in the FDA commitment letter, FDA will hold an annual meeting with stakeholders to review and evaluate implementation of the user fee program. FDA held the first annual meeting on December 3, 2003. The 2004 meeting is scheduled for November 18, 2004; FDA will provide additional information in the *Federal Register* and on our Internet site.

- *GAO reports*. By July 1, 2003, 2004, and 2005, *if* appropriations for the fiscal year are below a certain level, GAO is to submit to Congress a report "describing whether and to what extent [FDA] is meeting the performance goals identified for such fiscal year" and whether FDA will meet future performance goals. Sections 738(g)(1)(A)(ii)(II) and 738(g)(1)(B)(ii)(II). GAO's report covering FY 2003 and FY 2004, *Data to Measure the Timeliness of Reviews of Medical Device Applications Are Limited* (August 2004), is available at www.fda.gov/cdrh/mdufma/reports/gao-04-1022.pdf.
- *Annual reports by FDA*. Beginning with FY 2003, § 103 of MDUFMA requires FDA to submit annual reports to Congress concerning —
    - Progress in achieving our performance goals; this information is due November 30 of each year. FDA's report covering FY 2003 is available at www.fda.gov/oc/mdufma/perfreport2003/default.htm.
    - Implementation of the authority for fees, and the use we make of fee revenues; this information is due January 31 of each year. FDA's report covering FY 2003 is available at www.fda.gov/oc/mdufma/finreport2003/financial-fy2003.html.

Sunset. FDA's authority to collect medical device review fees expires October 1, 2007. § 107.

Inspections by Accredited Persons (Third-Party Inspections)

Background. MDUFMA § 201 and MDTCA § 2(b)(1) amend section 704 of the FD&C Act to authorize FDA-accredited persons to inspect qualified manufacturers of class II and class III devices. An eligible establishment is permitted to select any FDA-accredited person to conduct an inspection in lieu of an FDA inspection, but FDA must approve each selection. See sections 704(g)(1) and 704(g)(6)(B). An inspection by an accredited persons is often referred to as a "third-party inspection."

A third-party inspection may be completed in stages over a two-year period, section 704(g)(6)(A)(ii). This allows 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.

Publication of criteria for accreditation and review of requests for accreditation. As required by section 704(g)(2), FDA has published a *Federal Register* notice that provides the criteria we use to accredit a third-party to conduct inspections of class II and class III device manufacturers. See 68 F.R. 22400 (April 28, 2003). We have also published a guidance document, *Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria*, that explains our accreditation criteria in more detail. The current guidance (dated October 4, 2004; this edition replaces an earlier edition dated April 28, 2003) is available at —

Text format: www.fda.gov/cdrh/mdufma/guidance/1200.html
PDF format: www.fda.gov/cdrh/mdufma/guidance/1200.pdf

Within 60 days of receiving a request for accreditation, FDA must inform the requestor "whether the request for accreditation is adequate for review." Section 704(g)(2). No specific timeframe is set for an FDA accreditation decision, but we are to "promptly act on the request." *Id*.

FDA must publish, on the Internet, a complete list of accredited persons, and the activities for which they are accredited. Section 704(g)(4). FDA provides the current list of accredited persons at www.fda.gov/cdrh/ap-inspection/ap-inspection.html#list.

An establishment that employs an accredited person is responsible for compensation of that person. Section 704(g)(8). FDA does not pay for third-party inspections, and does not set the fees that may be charged by a third-party for an inspection.

Minimum requirements for accreditation. Section 704(g)(3) requires all accredited persons to meet certain criteria. An accredited person —

- May not be an employee of the Federal Government.
- May not be owned by, controlled by, or have an "affiliation (including a consultative affiliation)" with a manufacturer, supplier, or vendor of any product regulated by FDA.
- Cannot be engaged in the design, manufacture, promotion, or sale of FDA-regulated products.
- Must operate "in accordance with generally accepted professional and ethical business practices" and must agree in writing to certain fundamental operating principles.
- May not have a financial conflict of interest regarding any FDA-regulated product.

FDA audits of accredited persons. FDA is to conduct "periodic" audits to ensure accredited persons "continue to meet the standards of accreditation." Section 704(g)(5)(A). We may, for example, withdraw our accreditation (following an opportunity for an informal hearing) if we find an accredited person is "substantially not in compliance" with our accreditation criteria, has failed to act "in a manner that is consistent" with the act, or has a financial conflict of interest with an establishment it has inspected. Section 704(g)(5)(B). FDA may also temporarily suspend our accreditation pending an opportunity for an informal hearing. *Id*.

Not all establishments are eligible for inspection by an accredited person. To employ an accredited person in lieu of an FDA inspection, an establishment must meet certain conditions, including:

- The establishment must intend to manufacture class II or class III devices. Section 704(g)(1).
- The establishment must market a device in the United States *and* must market a device "in one or more foreign countries." Section 704(g)(6)(A)(iii).

The intent of these provisions is to focus the use of third-party inspections on firms that operate in a global market that currently involves multiple inspection requirements.

The most-recent inspection of the establishment must have been classified by FDA as "no action indicated" or "voluntary action indicated." Section 704(g)(6)(A)(i). An establishment where FDA has found more serious problems will not be eligible for third-party inspections.

The establishment must notify FDA of its proposed selection of an accredited person. The establishment must notify FDA of the person it intends to use, and FDA must agree to the selection. Section 704(g)(6)(A)(ii). This notification must also show that the government of the foreign country in which the device is to be marketed would recognize an inspection by the accredited person, *or* the law of that foreign country would recognize an inspection by FDA. *Id*.

FDA determination that an establishment is not eligible for inspection by an accredited person. If FDA determines the establishment is not eligible to have a third-party inspection

because it does not meet the statutory requirements, the establishment may, within 30 days of FDA's denial, request a review of FDA's decision. The review will be conducted by a person designated by FDA, and will begin within 30 days of the request for review. Section 704(g)(6)(B)(vi).

Restriction on repeated use of accredited persons instead of FDA. An establishment may not use accredited persons for more than four years (two complete third-party inspections, each completed within a two-year period) *unless* the establishment petitions FDA for a waiver and FDA approves the additional third-party inspection. Section 704(g)(6)(A)(iv)(I). This provision is intended to ensure periodic inspection by FDA, while avoiding penalizing companies who are prepared for an inspection before FDA can conduct it.

There are two paths to "approval" of a petition allowing an establishment to be inspected by accredited persons for an additional two-year period. One path requires explicit FDA approval, the other is automatic. The most important features of each path are —

FDA may grant the petition if . . .	*The petition is "deemed to be granted" if . . .*
• The petition states a commercial reason for the waiver. • FDA determines the public health would be served by a waiver. • FDA inspected the establishment within the past four years.	• Within 18 months of the last inspection, the establishment requested an FDA inspection. • FDA did not inspect the establishment within 30 months of the last inspection.

After an establishment has been permitted to use an accredited person for an additional two years, FDA *must* conduct the next inspection of the establishment. Section 704(g)(6)(A)(iv)(I). After FDA has inspected the establishment, the establishment may again use an accredited person if it meets the normal requirements that apply to third-party inspections.

FDA action on an establishment's notice that it intends to employ an accredited person. When an establishment provides notice to FDA under section 704(g)(6)(A) that it intends to use a third-party to conduct an inspection, FDA must respond within 30 days. If FDA fails to respond to a notice within 30 days, the establishment is deemed to have FDA clearance to use the accredited person it selected. Section 704(g)(6)(B)(i). FDA's response to a notice may —

- Approve the use of the selected third-party, section 704(g)(6)(B)(i); *or*

- Request additional information, including –
    - *Compliance data* showing whether the establishment has consistently complied with good manufacturing practice and promptly corrected any problems; this data must include complete reports of GMP inspections or other quality audits made during the preceding two years. The establishment is responsible for providing this information when FDA requests it. Sections 704(g)(6)(B)(ii)(I) and (B)(iii).
    - *Information on the relationship between the establishment and the third-party*, including information on previous inspections of the establishment or any related establishments; FDA may request this information from either the establishment or the third-party. Section 704(g)(6)(B)(ii)(II).

When FDA requests additional information, we must provide or deny clearance to use the selected third-party within 60 days of receiving the additional information. If we deny the request, we must state our reasons. If we do not make a decision within 60 days, the establishment is "deemed" to have FDA clearance to use the selected third-party. Sections 704(g)(6)(B)(iv) and (v).

FDA denial of use of an accredited person. If FDA denies an establishment's selection of an accredited third-party, the establishment may submit another notice, selecting a different third-party. This notice is treated in the same manner as an original request. Section 704(g)(6)(B)(v)(II).

FDA oversight. FDA will review all reports of inspection made by a third-party, and FDA retains the responsibility for making the final compliance determination following each inspection.

Effect of a finding of "official action indicated" following an inspection by an accredited person. If an establishment receives an "official action indicated" following an inspection by an accredited person, that establishment may use an accredited person for a subsequent inspection only if —

- The establishment is otherwise eligible for inspection by an accredited person;
- FDA issues a "written statement" that the violations that required action have been resolved; and
- Upon petition of the establishment, or FDA's own initiative, FDA informs the establishment that it has clearance to use an accredited person for inspections. If the establishment submits a petition, FDA must respond within 30 days.

See section 704(g)(6)(C)(i).

If FDA does not inspect such an establishment within 48 months of its petition to use a third-party, the establishment is eligible for inspection by an accredited person. Section 704(g)(6)(C)(ii).

Report of inspection by an accredited person. An inspection by an accredited person must be recorded in writing, "in a form and manner consistent with" FDA inspection reports. Section 704(g)(7)(A). The report must, among other things, describe each observation, identify matters that may affect compliance with the FD&C Act, and describe any recommendations made by the inspector. Section 704(g)(7)(B). A copy of the report is to be provided to FDA and to the establishment within three weeks of the end of the inspection. Section 704(g)(7)(C).

If an inspection finds a "condition that could cause or contribute to an unreasonable risk to the public health," the accredited person must *immediately* report the problem to FDA. Section 704(g)(7)(E).

False statements to an accredited person. An employee or agent of an establishment who makes a false statement to an accredited person is subject to fine or imprisonment under 18 U.S.C. 1001. Section 704(g)(7)(D).

FDA may continue to inspect any establishment. FDA retains authority to "inspect any device establishment pursuant to this Act." Section 704(g)(9).

Suspension of program. For each fiscal year beginning with FY 2005, if obligations for FDA-conducted inspections of device establishments fall below certain levels, no third-party inspections may be conducted during that fiscal year. Section 704(g)(10)(A). This provision is intended to protect FDA's current resources dedicated to Quality Systems inspections and to ensure that third-party inspections add to the number of inspections FDA would otherwise be able to perform. Section 704(g)(10)(B) requires GAO to conduct a study to determine the baseline appropriation amount to be applied under this provision. GAO's report, *Data to Measure the Timeliness of Reviews of Medical Device Applications Are Limited* (August 2004), is available at www.fda.gov/cdrh/mdufma/reports/gao-04-1022.pdf.

GAO report and recommendation. GAO is to submit a report on the third-party inspection program by October 26, 2006 (within four years of enactment of MDUFMA). The report is to include a recommendation as to whether the program should be continued or terminated. Section 704(g)(12).

Effect on agreements with foreign governments. The provisions for inspections by accredited persons have no legal effect on international agreements (such as the Mutual Recognition Agreement) described in section 803(b) of the FD&C Act. Section 704(g)(14).

Sunset. The authority for inspections by accredited persons expires October 1, 2012. Section 704(g)(11).

Reprocessed Single-Use Medical Devices

§ 302 of MDUFMA provides new regulatory requirements for reprocessed single-use devices.

Definitions. § 302(d) provides definitions for —

- *single-use device* – "means a device that is intended for one use, or on a single patient during a single procedure." This definition appears at section 201(ll)(1) of the FD&C Act.
- *reprocessed* – "with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use . . . The subsequent processing and manufacture . . . shall result in a device that is reprocessed within the meaning of this definition." Section 201(ll)(2)(A).
- *original device* – "means a new, unused single-use device." Section 201(ll)(3).
- *critical reprocessed single-use device* – "means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use." Section 201(mm)(1).
- *semi-critical reprocessed single-use device* – "means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body." Section 201(mm)(2).

Labeling requirements. § 302(a)(1) adds new section 502(v) to the FD&C Act to require reprocessed single-use device to "prominently and conspicuously" bear the statement:

> Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device].

Section 502(v) went into effect January 26, 2004 (15 months after enactment); its requirements apply only to devices "introduced or delivered for introduction into interstate commerce after such effective date." See § 302(a)(2).

Reconsideration of prior exemptions from 510(k). Section 510(o)(2)(A) requires FDA to review all critical or semi-critical reprocessed devices that were exempt from 510(k), and to identity those whose exemption from 510(k) should be ended. Section 510(o)(2)(C) also requires FDA to publish lists of those devices in the *Federal Register*. Termination of an exemption for a *reprocessed* device does not affect the 510(k) exemption for the *original* device. Section 510(o)(2)(E).

Validation data required for certain existing 510(k)s. Section 510(o)(1)(A) requires FDA to identify the types of reprocessed single-use devices already subject to 510(k) clearance for which FDA will require "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . .

after the maximum number of times the device is reprocessed as intended" by the person who submits the 510(k).

***Federal Register* Notices**. On April 30, 2003 and June 26, 2003, FDA published *Federal Register* notices identifying the *critical* reprocessed single-use devices whose prior exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). On April 13, 2004, we published a *Federal Register* notice identifying the *semi-critical* reprocessed single-use devices whose prior exemption from 510(k) is terminated, and for which validation data is now required in a 510(k).

If a 510(k) for a reprocessed device was submitted before FDA publishes the list required by section 510(o)(1)(A), the 510(k) holder must submit validation data "not later than nine months after the publication of the list." Section 510(o)(1)(B). If the device is otherwise in compliance with the act, marketing may continue during the nine-month grace period, and if a 510(k) is submitted, marketing may continue until such time as —

- the 510(k) is withdrawn by the applicant; or
- FDA finds the device is not substantially equivalent to a predicate device.

All 510(k)s for devices on FDA's list must now include validation data.

If FDA finds the device to be NSE (or it is withdrawn), it may no longer be marketed. Section 510(o)(1)(B).

Deadline for submission of 510(k)s where an exemption has ended. A 510(k) for a device whose exemption from premarket notification has ended must be submitted to FDA within 15 months of the date FDA published a list that included the device. If the device is otherwise in compliance with the act, marketing may continue during a 15-month grace period, and once a 510(k) is submitted, marketing may continue until such time as —

- the 510(k) is withdrawn by the applicant; or
- FDA finds the device is not substantially equivalent to a predicate device.

Section 510(o)(2)(B).

Deadline for submission of validation data where a 510(k) has already been submitted. The 2003 *Federal Register* notices also included the list of devices, already subject to 510(k) submission requirements, that now require the submission of validation data. If a 510(k) for a reprocessed device was submitted before FDA published this list, the 510(k) holder must submit validation data within nine months of the date of the notice. Section 510(o)(1)(B).

If the device is otherwise in compliance with the act, marketing may continue during a nine-month grace period. If a 510(k) has been submitted before the end of the grace period, marketing may continue until —

- the applicant withdraws the 510(k) submission, or
- FDA completes its review and finds the device is "not substantially equivalent" to a legally-marketed predicate device.

Section 510(o)(1)(B).

FDA guidance on validation data. FDA has published a guidance document that describes the types of validation data FDA recommends be included in a 510(k) for a reprocessed single-use device. See —

- *Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices*
  Text format: www.fda.gov/cdrh/ode/guidance/1216.html
  PDF format: www.fda.gov/cdrh/ode/guidance/1216.pdf

Premarket Report. Section 302(c) creates a new category of premarket submission, the premarket report. A premarket report must be submitted for a class III device that is a reprocessed single-use device that previously required a PMA. See amended § 515(c)(2)(A). Section 515(c)(2)(A) specifies the contents of a premarket report.

Revision of MedWatch forms. § 303 of MDUFMA required FDA to revise our MedWatch problem reporting forms "to facilitate the reporting of information . . . relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused." Revised forms are now available from FDA's MedWatch Internet site, www.fda.gov/medwatch.

Additional Provisions

Postmarket Surveillance

MDUFMA § 104(a) authorizes additional appropriations for postmarket surveillance — $3 million for FY 2003, $6 million for FY 2004, and "such sums as may be necessary" in subsequent years. *Note:* In addition to this authorization, Congress would have to pass an appropriations act before FDA would receive any portion of these additional sums.

§ 104(b) requires FDA to conduct, and submit to Congress by January 10, 2007, a study of —

- The effect of medical device user fees on FDA's ability to 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 extended beyond FY 2007.

Third-Party Review of 510(k)s

MDUFMA § 202 revoked the sunset date for third-party review of 510(k)s previously found in section 523(c) and replaced it with a new sunset date of October 1, 2007. New § 523(d) requires FDA to study the third-party review program, and to submit a report to Congress by January 10, 2007.

Debarment of Accredited Persons

MDUFMA § 203 adds new section 306(m) to the FD&C Act, providing for mandatory debarment of an accredited person who has been convicted of a felony under section 301(gg). The debarment of an individual is permanent, section 306(m)(2)(B), while a corporation or other legal entity shall be debarred for 1 to 10 years, and upon a second conviction, the debarment is permanent. Section 306(m)(2)(A). Under certain circumstances, a debarment may be terminated. Section 306(m)(3).

Combination Products

MDUFMA § 204 establishes an Office, within the Office of the Commissioner, to "ensure the prompt assignment of combination products to agency centers," timely and effective premarket reviews, and effective postmarket regulation. Section 503(g)(4)(A). FDA established the Office of Combination Products to undertake this responsibility; see www.fda.gov/oc/combination for additional information about the office and its activities.

Report on Devices Reviewed by Centers other than CDRH

MDUFMA § 205 requires FDA to study "the timeliness and effectiveness of device premarket reviews" by FDA centers *other than* CDRH. The most important requirement is that this report "shall include . . . specific recommendations on whether responsibility for regulating such devices should be reassigned" within FDA.

FDA completed this report in August 2003 and submitted it to Congress. FDA's report is available at www.fda.gov/cber/mdufma/report0803.pdf.

Electronic Labeling

§ 206 of MDUFMA and § 2(b)(2)(B) of MDTCA amend section 502(f) of the FD&C Act to permit device labeling to be provided "solely by electronic means" for —

- Prescription devices intended for use by a health care professional, regardless of the setting in which the device is used.
- Prescription devices intended for use in a health care facility.
- *In vitro* diagnostic devices intended for use by a health care professional, regardless of the setting in which the device is used.
- *In vitro* diagnostic devices intended for use in a blood establishment.

The electronic labeling must comply with all other requirements of the FD&C Act; and a manufacturer who uses electronic labeling must "promptly" provide a paper copy of the labeling upon request, at no additional charge.

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.

Electronic Registration

MDUMFA § 207 adds new section 510(p) to the FD&C Act, permitting FDA to require establishment registration "by electronic means" when feasible. FDA is permitted to grant requests for waivers from electronic registration.

FDA has not yet proposed to require electronic registration of device establishments.

Intended Use Shall be Based on Proposed Labeling

Under section 513(i)(E), when FDA reviews a 510(k) premarket notification, our determination of the intended use of the device "shall be based upon the proposed labeling" provided by the applicant. MDUFMA § 208 revoked a sunset provision that previously applied to section 513(i)(E). The effect is to make the requirement permanent.

FDA has published a guidance document explaining our approach to determining intended use for devices reviewed under the 510(k) premarket notification program; see —

- *Determination of Intended Use for 510(k) Devices*
  Text format: www.fda.gov/cdrh/ode/guidance/857.html
  PDF format: www.fda.gov/cdrh/ode/guidance/857.pdf

Modular Review

MDUFMA § 209 amends section 515(c) to create a modular review program for PMAs. FDA may suspend the program during any fiscal year where our authority to collect user fees has been suspended (*e.g.*, because appropriations did not meet required levels). Section 515(c)(3)(A). If FDA determines that a modular submission is unacceptable, we must provide the applicant a written description of its deficiencies and identify the information needed to correct those deficiencies. Section 515(c)(3)(C).

FDA guidance explains how to submit a modular PMA and how FDA will review modular submissions; see —

- *Premarket Approval Application Modular Review*
  Text format: www.fda.gov/cdrh/mdufma/guidance/835.html
  PDF format: www.fda.gov/cdrh/mdufma/guidance/835.pdf

Under the FDA commitment letter, FDA will work with stakeholders to develop performance goals for modular reviews. Until specific performance goals are developed, FDA will complete our review of individual modules in as little time as is reasonably possible.

Internet List of Devices Exempted from 510(k)

MDUFMA § 211 amends section 510(m)(1) to require FDA to post on the Internet the list of class II devices we have exempted from 510(k), and to update the Internet posting within 30 days of any revision of the list. This list is now available at —

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

Provisions Relating to Devices Intended for Pediatric Use

Pediatric expertise on advisory panels. MDUFMA § 210 amends section 515(c) to require, where appropriate, that each medical device advisory panel "includes, or consults with, one or more pediatric experts." FDA has published guidance outlining our procedures to ensure that our advisory panels will appropriately include or consult with pediatric experts; see —

- *Pediatric Expertise for Advisory Panels*
  Text format: www.fda.gov/cdrh/ode/guidance/1208.html
  PDF format: www.fda.gov/cdrh/ode/guidance/1208.pdf

IOM study. MDUFMA § 212 requires FDA to request the Institute of Medicine "enter into an agreement" to conduct a study of whether the FD&C Act's provisions for postmarket surveillance provide "adequate safeguards regarding the use of devices in pediatric populations." See §§ 212(a) and (b). The Institute is now conducting this study, and is to report its findings to FDA during 2005.

FDA report. By October 26, 2006 (within four years of enactment), FDA must submit a report to Congress concerning IOM's findings (see above) and any recommendations we have "for administrative or legislative changes to the system of postmarket surveillance" for pediatric devices. § 212(c).

FDA guidance. MDUFMA § 213 required FDA to issue guidance on —

- The types of information necessary to reasonably assure the safety and effectiveness of devices used in pediatric populations.
- Protection of children who participate in clinical trials of devices.

FDA has published a guidance document that 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 —

- *Premarket Assessment of Pediatric Medical Devices*
  Text format: www.fda.gov/cdrh/mdufma/guidance/1220.html
  PDF format: www.fda.gov/cdrh/mdufma/guidance/1220.pdf.

Provisions Relating to Breast Implants

GAO study. MDUFMA § 214 requires GAO to conduct a study concerning —

- The adequacy of information provided to women who are considering breast implant surgery or who participate in clinical trials, how that information is provided, and when.
- The number of adverse events reported, and whether they have been adequately investigated.

Section 214 does not specify the date when GAO must submit its report to Congress.

NIH research. MDUFMA § 215(a) requires NIH to submit to Congress a report "describing the status of research on breast implants . . . conducted or supported" by NIH. The NIH report to Congress is available at www4.od.nih.gov/orwh/implants.pdf.

§ 215(b) amends the Public Health Service Act to authorize NIH to conduct or support research on "the long-term health implications of silicone breast implants, both gel and saline filled."

Identification of Device Manufacturer

MDUFMA § 301(a) adds new section 502(u) to the FD&C Act, to 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 unique symbol. FDA may waive this requirement for a device if it is "not feasible" or if it would compromise its safety or effectiveness. A device that does not bear the name of the manufacturer when required is misbranded.

Section 502(u) goes into effect October 26, 2005 (36 months after enactment of MDUFMA), and its requirements apply only to devices "introduced . . . into interstate commerce after such effective date." See § 301(b) of MDUFMA and § 2(c)(1) of MDTCA.

FDA has determined that effective implementation of section 502(u) is not feasible until FDA provides guidance to industry to explain how FDA will interpret and apply the new provision and the circumstances under which a manufacturer may obtain a waiver of the requirement. Accordingly, we have issued draft guidance to advise industry that we will exercise enforcement discretion and will not object if a manufacturer does not make 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 this new requirement; see —

- *Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 – Identification of Manufacturer of Medical Devices* — Draft Guidance
  Text format: www.fda.gov/cdrh/comp/guidance/1217.html
  PDF format: www.fda.gov/cdrh/comp/guidance/1217.pdf

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