Summary of the
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Center for Devices and Radiological Health

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Summary: 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.

The act has three particularly significant provisions:

- ***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. Fees will add $25.1 million to FDA's medical device budget authority during FY 2003, rising to $35 million in FY 2007. These sums are protected from inflation and changes in workloads through a set of adjustments. The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of ambitious performance goals; these goals will be summarized in letters from Secretary Thompson to Congress and are incorporated by reference in the new law. The payment of a premarket review fee is not related in any way to FDA's final decision 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.

- Additional provision of the new law include:

    - The third-party 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.
    - Electronic labeling is authorized for prescription devices intended to be used in health care facilities.
    - FDA may require electronic registration of device establishments, when feasible.
    - The sunset provision applicable to section 513(i)(1)(E) (intended use based upon labeling) is revoked.
    - The law now explicitly provides for modular review of PMAs.
    - New provisions are added concerning devices intended for pediatric use.
    - The act 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.
    - GAO and NIH are directed to prepare reports concerning breast implants.

- The manufacturer of a device must be identified on the device itself, with certain exceptions.

Background. The law recognizes 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 section 101.

Contents. The law includes —

Wherever possible, citations below are to sections of the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002. Medical device user fee authority will now be found in sections 737 and 738 of the FD&C Act. Citations to section numbers 101 - 107 refer to MDUFMA.

Section 102 authorizes FDA to assess fees for the premarket review of —

- PMAs, PDPs, premarket reports (this is 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. See section 106.

Fee revenues will support the "process for the review of device applications," § 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 premarket guidance, policy documents, and regulations,
- 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.

Specific FDA performance goals will be set in a "goals letter" to House and Senate committees. This letter will be published in the *Congressional Record*.

Fee Structure and Initial Fees				
		Initial Fee (FY 2003)		
			Small Business Applicant ($30 million threshold)	
Application	Fee Structure[1] (Percent of Baseline Fee)	Standard Fee	Percent of Standard Fee[2]	Small Business Fee
Premarket application (PMA, PDP, BLA)	Baseline Fee (100%)	$154,000[3]	38%	$58,520
Premarket report[4]	100%	$154,000	38%	$58,520
Panel-track supplement	100%	$154,000	38%	$58,520
Efficacy supplement	100%	$154,000	38%	$58,520
180-day supplement	21.5%	$33,110	38%	$12,582
Real-time supplement	7.2%	$11,088	38%	$4,213
510(k)	1.42%	$2,187	Not applicable during FY 2003; a small business fee for 510(k)s becomes effective FY 2004.	

Payment of fees. Fees are due when the premarket submission is made to FDA. When a modular submission is used, the entire fee is due with the first portion submitted to FDA. § 738(a)(1)(C). Special provision is made for submissions made between October 1, 2002 and the date of enactment, of enabling appropriations.

Qualification for small business fees and waivers. To qualify as a small business, the applicant's gross receipts or sales, including that of all affiliates, partners, and parent firms, cannot exceed $30 million. § 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 returns (and returns of all affiliates, partners, and parent firms). § 738(d)(2)(B) and § 738(e)(2)(B). FDA's

[1] § 738(a)(1)(A).

[2] § 738(d)(2)(C), except 510(k)s, § 738(e)(2)(C)(i).

[3] § 738(c)(5).

[4] This category applies to a PMA for a class III device that is a reprocessed single-use device. See § 515(c)(2)(A), as amended.

decision as to whether an applicant qualifies as a small business is not reviewable. § 738(d)(2)(D) and § 738(e)(2)(D).

Small business threshold. FDA can adjust the small business threshold (initially $30 million) 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. § 738(d)(2)(A)(ii). For example, if the $30 million small business threshold results in the loss of too much revenue, FDA will be able to change the threshold to a level (some number less than $30 million) that will result in a revenue stream that better meets the expectations and intent of Congress.

Fee Exemptions and Waivers	
Category	**Exemption or Waiver**
HDE	Exempt from any fee. § 738(a)(1)(B)(i).
BLA for a product licensed for further manufacturing use only	Exempt from any fee. § 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. § 738(d)(1).
First premarket report (PMR) 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 the new law.
Third-party 510(k)	Exempt from any FDA fee; however, the third-party may charge a fee for its review. § 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. § 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. § 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. § 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. § 738(i).

Refunds. Refunds may be available under certain circumstances for PMAs, PMRs and supplements. Upon written request made within 180 days after the fee is due, § 738(j), FDA is to refund 75% of a paid fee if we refuse to file a submission, or if the applicant withdraws a submission prior to our filing decision. § 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.
§ 738(a)(1)(D)(iii). FDA will not make any refunds following the agency's first action on a submission. ("First action" means major deficiency, not approvable, approvable, approvable pending GMP inspection, or denial.)

Publication of fees. Fees for FY 2004 and later years are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.

Performance Goals. Section 738(g) requires FDA to meet performance goals defined in the user fees goals letter. In a fiscal year where appropriations for salaries and expenses for devices and radiological health do not meet certain levels (essentially, our current appropriation, increased by adjustment factors defined in the bill), FDA is "expected to meet such goals to the extent practicable, taking into account the amounts that are available . . . for such purpose." 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 performance goals for that year.

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

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal)				
		2003	2004	2005	2006	2007
PMAs, Panel-Track Supplements, and PMRs						
• 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%

FDA Performance Goals Under the Medical Device User Fee and Modernization Act of 2002						
		Performance Level (by FY) (— indicates no quantitative goal)				
• 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%
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 Supplements						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	—	80%	85%	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%
Biologics Licensing Applications – BLAs						
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	—	—	75%	80%	90%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	—	—	75%	80%	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 Resubmssions, 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%

Sunset. FDA's authority to collect fees under the act expires October 1, 2007.

Oversight of user fee provisions. The act provides for several oversight mechanisms.

- ***Annual stakeholders' meeting***. Beginning in FY 2004, the goals letter requires an annual meeting with stakeholders to review and evaluate implementation of the user fee program.
- ***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. § 738(g)(1)(A)(ii)(II) and § 738(g)(1)(B)(ii)(II).
- ***Annual reports by FDA***. Beginning with FY 2003, section 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.
  - implementation of the authority for fees, and the use we make of fee revenues; this information is due January 31 of each year.

Revenues (Appropriated Amounts) from User Fees

Fee Revenue Targets (Unadjusted)	
Year	**Revenues**
FY 2003	$25,125,000
FY 2004	$27,255,000
FY 2005	$29,785,000
FY 2006	$32,615,000
FY 2007	$35,000,000

Adjustments to Fee Revenue Targets

Revenue targets will be increased each year to account for –

- Inflation
- Increased workload throughout the "process for the review of device applications."
- Shortfalls in fee revenue below the previous year's adjusted revenue target.
- A special adjustment in FY 2007 (final year adjustment).
- Legislation requiring DHHS to fund additional employee retirement cost, if such legislation is subsequently enacted.

Postmarket Surveillance

Section 104(a) of 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. *Note:* For FDA to actually receive these resources, Congress must pass appropriations acts providing these additional funds to the agency.

Section 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.

Wherever possible, citations below are to sections of the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002. The authority for inspections by accredited persons will be found at section 704 of the FD&C Act. Citations to section numbers 201 - 203 refer to the Medical Device User Fee and Modernization Act of 2002.

Section 201 of MDUFMA amends section 704 of the FD&C Act to authorize FDA-accredited persons to inspect qualified manufacturers of class II and class III devices.

Publication of criteria for accreditation and review of requests for accreditation. Section 704(g)(2) requires FDA to publish, within 180 days of the enactment of the Medical Device User Fee and Modernization Act of 2002, criteria for the accreditation of third-parties to conduct inspections of class II and class III device manufacturers. Within one year of enactment, FDA must accredit third-parties; an eligible establishment would then be permitted to select any accredited person to conduct an inspection in lieu of an FDA inspection. § 704(g)(1).

Within 60 days of receiving a request for accreditation, FDA must inform the requestor "whether the request for accreditation is adequate for review." § 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. § 704(g)(4). During the first year of the program, FDA may accredit no more than 15 persons. § 704(g)(2).

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

Minimum requirements. 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, or have an "affiliation (including a consultative affiliation)" with a device manufacturer, supplier, or vendor.
- 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." § 704(g)(5)(A). If the accredited person is

"substantially not in compliance" with FDA's accreditation criteria or otherwise "fails to act in a manner that is consistent" with the act, FDA may, following an opportunity for an informal hearing, withdraw an accreditation. § 704(g)(5)(B). FDA may also temporarily suspend an 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:

- The most-recent inspection must have been classified as "no action indicated" or "voluntary action indicated." § 704(g)(6)(A)(i).
- The establishment must notify FDA of the person it intends to use, and FDA must agree to the selection. § 704(g)(6)(A)(ii).
- The establishment must market a device in the United States *and* must market a device "in one or more foreign countries." § 704(g)(6)(A)(iii).
- The accredited person must be certified, accredited, or otherwise recognized by one of the countries in which the device is to be marketed. *Id.*
- The establishment must submit a statement that one of the countries in which the device is to be marketed "recognizes an inspection of the establishment by [FDA]." *Id*.

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

Restriction on repeated use of accredited persons instead of FDA. An accredited person cannot be used for three consecutive inspections of a particular establishment unless the establishment petitions FDA for a waiver. § 704(g)(6)(A)(iv)(I). This provision is intended to encourage periodic inspections by FDA, while avoiding penalizing companies who are prepared for an inspection before FDA can conduct it. There are two paths for "approval" of a waiver petition allowing continued use of accredited persons to conduct inspections, one requiring explicit FDA approval, the other automatic —

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; and • FDA inspected the establishment within the past four years.	• The petition states a commercial reason for the waiver; • Within 18 months of the last inspection, the establishment requested an FDA inspection; and • FDA did not inspect the establishment within 30 months of the last inspection.

FDA action on an establishment's notice that it intends to employ an accredited person. When an establishment provides notice to FDA under § 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 . . . clearance" to use the accredited person it selected. § 704(g)(6)(B)(i). FDA's response to a notice may —

- approve the use of the selected third-party, § 704(g)(6)(B)(i); *or*
- request additional information concerning –
  - *compliance data* showing whether the establishment has consistently complied with good manufacturing practice requirements and promptly corrected any problems; this data must include complete reports of inspections or other quality audits made during the preceding two years. The establishment is responsible for providing this information. § 704(g)(6)(B)(ii)(I) and (B)(iii).
  - *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. § 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 from the establishment. If we deny the request, we must state our reasons. If we neither clear nor deny use of the third-party, the selection is "deemed" to have been accepted. § 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. § 704(g)(6)(B)(v)(II).
- request a review of FDA's decision within 30 days of FDA's denial. This review will be conducted by "a person" designated by FDA and will begin within 30 days of the request for review. § 704(g)(6)(B)(vi).

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 OAI violations 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. § 704(g)(6)(C)(i).

If FDA does not inspect such an establishment within 48 months of a request to use a third-party, the establishment is eligible for inspection by an accredited person. § 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. § 704(g)(7)(A). The report must, among other requirements, describe each observation, identify matters that may

influence compliance with the FD&C Act, and describe any recommendations made by the inspector. § 704(g)(7)(B). A copy of the report is to be provided to FDA within three weeks of the end of the inspection. § 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. § 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. § 704(g)(7)(D).

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

Suspension of program. Beginning with FY 2005, if appropriations to FDA for a given fiscal year fall below certain levels, no third-party inspections may be conducted during that fiscal year. § 704(g)(10). This provision is intended to protect FDA's current resources dedicated to Quality Systems inspections and to ensure that third party inspections supplement the number of inspections FDA would otherwise be able to perform.

Reports. GAO is to submit a report on the third-party inspection program within four years of enactment. The report is to include a recommendation as to whether the program should be continued or terminated. § 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. § 704(g)(14).

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

Reprocessed Single-Use Medical Devices

Section 302 provides new regulatory requirements for reprocessed single-use devices.

Definitions. Section 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." § 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 . . . 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." § 201(ll)(2)(A).
- *original device* – "means a new, unused single-use device." § 201(ll)(3).
- *critical reprocessed device* – "means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use." § 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." § 201(mm)(2).

Labeling requirements. Section 302(a)(1) adds new § 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].

§ 502(v) goes into effect 15 months after enactment, and its requirements apply only to devices "introduced . . . into interstate commerce after such effective date." See section 302(a)(2).

Submission of validation data for devices subject to 510(k) (i.e., not exempt). Within six months of enactment, FDA is to review the types of reprocessed single-use devices that currently are the subject to 510(k) clearance and identify those 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). § 510(o)(1)(A). FDA must publish a list of those devices in the *Federal Register*, and must update the list as appropriate. *Id.* All new 510(k)s for devices on FDA's list must include validation data, as of the date the list is published.

If a 510(k) for a reprocessed single-use device was cleared before FDA publishes the list required by § 510(o)(1)(A), the 510(k) holder must submit validation data "not later than nine months after the publication of the list." § 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 new 510(k) is submitted, marketing may continue, unless the 510(k) is withdrawn by the submitter or FDA finds the device is not substantially equivalent to a predicate device. § 510(o)(1)(B).

Reconsideration of existing exemptions from 510(k). Section 510(o)(2)(A) requires FDA to review all critical or semi-critical reprocessed devices that are currently exempt from 510(k) to identity those whose exemption from 510(k) should be ended, and we must publish lists of those devices in the *Federal Register*. Section 510(o)(2)(C) requires these lists to be published no later than —

- within six months of the effective date — critical reprocessed devices for which 510(k)s with validation data will be required,
- within 18 months of the effective date — semi-critical reprocessed devices for which 510(k)s with validation data will be required.

510(k)s for devices that are no longer exempt from premarket notification must be submitted to FDA within 15 months of the date FDA publishes a list that includes the device. If the device is otherwise in compliance with the act, marketing may continue during the 15-month grace period and if a 510(k) is submitted, marketing may continue unless —

- the 510(k) is withdrawn by the submitter; or
- FDA finds the device is not substantially equivalent to a predicate device.
  § 510(o)(2)(B).

Termination of an exemption for a reprocessed device does not affect the exemption for the original device. § 510(o)(2)(E).

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 reprocessed single-use device that previously required a PMA. Section 515(c)(2)(A) specifies the contents of a premarket report.

Revision of MedWatch forms. Section 303 requires FDA to revise MedWatch 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."

Third-Party Review of 510(k)s

Section 202 of MDUFMA revokes the existing sunset provision found at § 523(c) of the FD&C Act and replaces 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

Section 203 of MDUFMA adds new § 306(m) to the FD&C Act for mandatory debarment of an accredited person who has been convicted of a felony under § 301(gg). The debarment of an individual is permanent, § 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, § 306(m)(2)(A). Under certain circumstances, a debarment may be terminated. § 306(m)(3).

Combination Products

Section 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. § 503(g)(4)(A) of the FD&C Act.

Report on Devices Reviewed by Centers other than CDRH

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

Electronic Labeling

Section 206 amends § 502(f) of the FD&C Act to permit prescription devices used in health care facilities to provide labeling "solely by electronic means" so long as —

- the labeling complies with all other requirements of the FD&C Act; and
- the manufacturer will "promptly" provide the facility a paper copy of the labeling upon request at no additional charge.

Electronic Registration

Section 207 adds new section 510(p), permitting FDA to require establishment registration "by electronic means," when feasible.

Intended Use Shall be Based on Proposed Labeling

Section 208 revokes the sunset provision for § 513(i)(E), which addresses how FDA is to determine the intended use of a device. The effect is to make the requirement permanent.

Modular Review

Section 209 amends § 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). § 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. § 515(c)(3)(C).

Internet List of Devices Exempted from 510(k)

Section 211 amends § 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.

Provisions Relating to Devices Intended for Pediatric Use

Pediatric expertise on advisory panels. Section 210 amends § 515(c) to require that, "[w]here appropriate, such panel includes, or consults with, one or more pediatric experts."

IOM study. Section 212 requires FDA to "enter into an agreement" with the Institute of Medicine for IOM 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 section 212(a) and (b).

FDA report. 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. Section 212(c).

FDA guidance. Within 270 days of enactment, FDA must issue guidance on —

- Information necessary to assure the safety and effectiveness of devices used in the pediatric population.
- Protection of children who participate in clinical trials of devices.

See section 213.

Provisions Relating to Breast Implants

GAO study. Section 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 reports and whether they have been adequately investigated.

NIH research. Section 215(a) requires NIH to submit to Congress a report "describing the status of research on breast implants . . . conducted or supported" by NIH. This report is due within 180 days of enactment.

Section 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

Section 301(a) of MDUFMA adds new § 502(o) 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 if it is "not feasible for the device or would compromise . . . the safety or effectiveness of the device."

Section 502(o) goes into effect 18 months after enactment, and its requirements apply only to devices "introduced . . . into interstate commerce after such effective date." See section 301(b).

A device that does not bear the name of the manufacturer when required is misbranded.