Federal Register Notices Concerning MDUFMA

Updated through *Federal Register* of September 9, 2004

Most-Recent Notices Listed First (Reverse Chronological Order)

Date	Subject	Citation	Comment / Action Date
8/2/2004	Establishment of Medical Device User Fee Rates for Fiscal Year 2005.	69 F.R. 46153	—
7/9/2004	Agency Emergency Processing Under OMB Review; Application for Participation in the Medical Device Fellowship Program (Form FDA 3608).	69 F.R. 41508	Comment period closed. (Comments were due by 8/9/2004)
6/24/2004	Definition of primary mode of action for a combination product.	69 F.R. 35277	Comment period closed. (Comments were due by 8/20/2004)
6/21/2004	Request for comments on possible barriers to the availability of devices intended to treat or diagnose diseases and conditions that affect children. This information will help FDA prepare a report to Congress required by section 3 of the Medical Devices Technical Corrections Act; the report is due to Congress 9/28/2004.	69 F.R. 34374	Comment period closed. (Comments were due by 8/20/2004)
6/3/2004	Availability of Draft Guidance — Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program. This guidance is available at — www.fda.gov/cdrh/comp/guidance/1532.pdf	69 F.R. 31397	Comment period closed. (Comments were due by 9/1/2004)
6/1/2004	Availability of Guidance — Validation Data in Premarket Notifications for Reprocessed Single-Use Medical Devices. This guidance supersedes the guidance provided 7/8/2003 (see above). The current edition is available at — www.fda.gov/cdrh/ode/guidance/1216.pdf	69 F.R. 30943	Submit comments at any time.
5/28/2004	Availability of Guidance — User Fees and Refunds for Premarket Notification Submissions (510(k)s). This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1511.pdf	69 F.R. 30672	Submit comments at any time.

Date	Subject	Citation	Comment / Action Date
5/21/2004	Availability of Guidance — FDA and Industry Actions on 510(k) Submissions – Effect on FDA Review Clock and Performance Assessment. This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1219.pdf	69 F.R. 29314	Submit comments at any time.
5/14/2004	Availability of Guidance — Premarket Assessment of Pediatric Medical Devices. Also see 7/24/2003 (availability of draft guidance). This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1220.pdf	69 F.R. 26868	Submit comments at any time.
5/7/2004	Proposed Rule — Definition of Primary Mode of Action for a Combination Product.	69 F.R. 25527	Comment period closed. (Comments were due by July 6, 2004)
5/4/2004	Availability of Draft Guidance — Combination Products – Timeliness of Premarket Reviews – Dispute Resolution Guidance. This guidance is available at — www.fda.gov/OHRMS/DOCKETS/98fr/04d-0182-gdl0001.pdf	69 F.R. 24653	Comment period closed. (Comments were due by July 6, 2004)
4/13/2004	Semicritical Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data. Provides list of semicritical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). Also see 4/30/2003 (*critical* reprocessed single-use devices).	69 F.R. 19433	Effective 4/13/2004; 510(k)s due 7/13/2005
2/17/2004	Announcing availability of revised MedWatch forms. The revised forms are available at — www.fda.gov/medwatch/getforms.htm	69 F.R. 7490	Prior versions of Forms 3500 and 3500A may be used until 8/17/2004.
	• 2/26/2004 — Correction — Provides omitted date.	69 F.R. 9028	—

Date	Subject	Citation	Comment / Action Date
1/9/2004	OMB Approval of Information Collection; MDUFMA Small Business Qualification Certification (Form FDA 3602). Approval expires December 31, 2006. Also see 7/18/2003 (60-day notice) and 10/10/2003 (submission to OMB).	69 F.R. 1588	—
12/9/2003	OMB Approval of Information Collection; Inspection by Accredited Persons Program Under MDUFMA. Approval expires November 30, 2006. Also see 7/10/2003 (60-day notice) and 10/8/2003 (submission to OMB).	68 F.R. 68632	—
11/26/2003	Availability of Guidance — Bundling Multiple Devices or Multiple Indications in a Single Submission. This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1215.pdf	68 F.R. 66461	Submit comments at any time.
11/26/2003	Availability of Guidance — Expedited Review of Premarket Submissions for Devices This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/108.pdf	68 F.R. 66463	Submit comments at any time.
11/24/2003	Availability of Guidance — User Fees and Refunds for Premarket Approval Applications. This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1224.pdf	68 F.R. 65940	Submit comments at any time.
11/6/2003	Availability of list of persons accredited to conduct Quality Systems / GMP inspections under MDUFMA. Also see 4/28/2003 (Availability of Guidance — Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria).	68 F.R. 62811	—
11/3/2003	Availability of Guidance — Premarket Approval Modular Review. This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/835.pdf	68 F.R. 62298	Submit comments at any time.

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10/10/2003	Submission of proposed information collection to OMB — MDUFMA Small Business Qualification Certification (Form FDA 3602). Revised version for use during FY 2004. Also see 7/18/2003 (60-day notice) and 1/9/2004 (OMB approval).	68 F.R. 58690	Comment period closed. (Comments were due by 11/10/2003.)
10/10/2003	OMB Approval of Information Collection; MedWatch Medical Products Reporting Program. FDA modified MedWatch forms to facilitate the reporting of information pertaining to reprocessed single-use devices. The existing MedWatch forms may be used for the next 6 months (though 4/6/2004). Approval expires March 31, 2005. Also see also 2/10/2003 (60-day notice) and 4/29/2003 (submission to OMB).	68 F.R. 58691	—
10/8/2003	Submission of proposed information collection to OMB — Inspection by Accredited Persons Program Under MDUFMA. Also see also 7/10/2003 (60-day notice) and 12/9/2003 (OMB approval).	68 F.R. 58113	Comment period closed. (Comment were due by 11/7/2003.)
9/29/2003	Notice of first Annual Stakeholder Meeting on Implementation of MDUFMA, to be held December 3, 2003.	68 F.R. 55967	Past event. (Registration ended 11/3/2003.)
8/28/2003	OMB Approval of Information Collection; Submission of Validation Data for Reprocessed Single-Use Devices. Approval expires 1/31/2004. Also see 7/8/2003 (emergency submission to OMB).	68 F.R. 51788	—
8/25/2003	OMB Approval of Information Collection; Medical Device User Fee Cover Sheet (Form FDA 3601). Approval expires 8/31/2006. Also see 2/26/2003 (60-day notice) and 5/21/2003 (submission to OMB).	68 F.R. 51023	—

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8/1/2003	Establishment of Medical Device User Fee Rates for Fiscal Year 2004.	68 F.R. 45246	—
7/24/2003	Availability of Draft Guidance — Premarket Assessment of Pediatric Medical Devices. Also see 5/14/2004 (availability of final guidance). The final guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1220.pdf	68 F.R. 43729	Comment period closed. (Comments were due by 10/23/2003.)
7/18/2003	Request for comments on proposed information collection — MDUFMA Small Business Qualification Certification (Form FDA 3602). (60-day notice.) Revised version for use during FY 2004. Also see 10/10/2003 (submission to OMB) and 1/9/2004 (OMB approval).	68 F.R. 42742	Comment period closed. (Comments were due by 9/16/2003.)
7/10/2003	Request for comments on proposed information collection — Inspection by Accredited Persons Program Under MDUFMA. (60-day notice.) Previously-approved information collection approval expires 9/30/2003; see 6/26/2003. Also see 10/8/2003 (submission to OMB) and 12/9/2003 (OMB approval).	68 F.R. 41160	Comment period closed. (Comments were due by 9/8/2003.)
7/8/2003	Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices. Also see 8/28/2003 (OMB approval).	68 F.R. 40676	Comment period closed. (Comments were due by 8/7/2003.)
	• 7/23/2003 — Correction — Corrects OMB contact information.	68 F.R. 43534	—
	• 8/20/2003 — Correction — Corrects docket number.	68 F.R. 50155	—
7/8/2003	Availability of Guidance — Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices. This guidance was revised 6/1/2004 (see below). The current edition is available at — www.fda.gov/cdrh/ode/guidance/1216.pdf	68 F.R. 40679	Submit comments at any time.
	• 7/23/2003 — Correction — Corrects docket number.	68 F.R. 43538	—

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6/26/2003	OMB Approval of Information Collection; Inspection by Accredited Persons Program Under MDUFMA. This approval expires 9/30/2003. Also see 4/28/2003 (emergency submission to OMB).	68 F.R. 38065	—
6/26/2003	Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data. Adds nonelectric biopsy forceps to the 4/30/2003 list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). Also clarifies deadline dates shown in 4/30/2003 notice. Also see 4/30/2003 (original list of critical reprocessed single-use devices).	68 F.R. 38071	Effective 6/26/2003; 510(k)s due 9/27/2004.
6/23/2003	Availability of Draft Guidance — Compliance with Section 301 of MDUFMA – Identification of Manufacturer of Medical Devices. This guidance is available at — www.fda.gov/cdrh/comp/guidance/1217.pdf	68 F.R. 37161	Comment period closed. (Comments were due by 9/22/2003.)
6/3/2003	Availability of Guidance — Pediatric Expertise for Advisory Panels. This guidance is available at — www.fda.gov/cdrh/ode/guidance/1208.pdf	68 F.R. 33166	Submit comments at any time.
5/21/2003	Submission of proposed information collection to OMB — Medical Device User Fee Cover Sheet; Form FDA 3601. Also see 2/26/2003 (60-day notice) and 8/25/2003 (OMB approval).	68 F.R. 27818	Comment period closed. (Comments were due by 6/30/2003.)
4/30/2003	Critical Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data. Provides list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). Also see 6/26/2003 (adding nonelectric biopsy forceps to the list	68 F.R. 23139	Effective 4/30/2003; 510(k)s due 7/30/2004; validation data for devices already cleared under 510(k) due 1/30/2004

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4/29/2003	Submission of proposed information collection to OMB — MedWatch: The FDA Medical Products Reporting Program. Also see also 2/10/2003 (60-day notice) and 10/10/2003 (OMB approval).	68 F.R. 22716	Comment period closed. (Comments were due by 5/29/2003.)
4/28/2003	OMB Approval of Information Collection; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602). This approval expires 10/31/2003 (form will not be used after 9/30/2003; see 7/18/2003 for notice on replacement form). Also see 3/26/2003 (emergency submission to OMB).	68 F.R. 22387	—
4/28/2003	Agency Emergency Processing Under OMB Review; Inspection by Accredited Persons Under MDUFMA. Also see 6/26/2003 (OMB approval).	68 F.R. 22388	Comment period closed. (Comments were due by 5/28/2003.)
4/28/2003	Availability of Guidance — Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria. This guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1200.pdf Also see 11/6/2003 (list of accredited persons).	68 F.R. 22400	Submit comments at any time.
3/27/2003	Availability of Guidance — Fiscal Year 2003 MDUFMA Small Business Qualification Worksheet and Certification. (This guidance announced in this Notice is now obsolete; it was replaced by new guidance for FY 2004. Because the FY 2004 guidance is a Level 2 guidance, no *Federal Register* Notice was required.) The FY 2004 guidance is available at — www.fda.gov/cdrh/mdufma/guidance/1225.pdf)	68 F.R. 14992	Submit comments at any time.
3/26/2003	Agency Emergency Processing Under OMB Review; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602). Also see 4/28/2003 (OMB approval).	68 F.R. 14664	Comment period closed. (Comments were due by 4/25/2003.)

Date	Subject	Citation	Comment / Action Date
2/26/2003	Request for comments on proposed information collection — Medical Device User Fee Cover Sheet; Form FDA 3601. (60-day notice.) Also see 5/21/2003 (submission to OMB) and 8/25/2003 (OMB approval).	68 F.R. 8907	Comment period closed. (Comments were due by 4/28/2003.)
2/25/2003	Medical Device User Fee Payment Procedures.	68 F.R. 8773	—
2/10/2003	Request for comments on proposed information collection —MedWatch: The FDA Medical Products Reporting Program. (60-day notice.) Section 202 of MDUFMA directs FDA to modify MedWatch forms to facilitate the reporting of information pertaining to reprocessed single-use devices. Also see 4/29/2003 (submission to OMB) and 10/10/2003 (OMB approval).	68 F.R. 6752	Comment period closed. (Comments were due by 4/11/2003.)
2/4/2003	Establishment of a Public Docket.	68 F.R. 5643	Submit comments at any time.
11/21/2002	Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and Interim Procedures.	67 F.R. 70228	—
	• 1/10/2003 — Correction — A 510(k) submitted during FY 2003 is not eligible for a reduced small business fee. Fee for any 510(k) submitted during FY 2003 is $2,187.	68 F.R. 1469	—
	• 1/22/2003 — Correction — Same intent.	68 F.R. 3033	—

Additional information —

A complete list of all of FDA's MDUFMA guidance documents, including those not announced in the *Federal Register*, is available at —

www.fda.gov/cdrh/mdufma/guidance

Each guidance document is available in plain text (html) and portable document format (pdf).

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