Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications

U.S. Food & Drug Administration

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This document supersedes "User Fees and Refunds for Premarket Approval Applications" dated November 24, 2003.

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For questions regarding submissions to the Center for Devices and Radiological Health (CDRH), contact the Premarket Approval Staff at 301-796-5640. For questions regarding submissions to the Center for Biologics Evaluation and Research, contact CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to http://www.regulations.gov [2]. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov [3] to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. Please use the document number 1681 to identify the guidance you are requesting.

Additional copies of this guidance document are also available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, by telephone, 1-800-835-4709 or 301-827-1800, by email, ocod@fda.hhs.gov [4], or from the Internet [5].

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User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

During the review of a premarket submission, the review clock is impacted by both FDA’s and Industry’s action. The Medical Device User Fee Amendments of 2012[1] [14] (MDUFA III), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2012, including premarket approval applications (PMAs) and certain biologics license applications (BLAs). The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the medical device review process to meet certain performance goals and implement improvements for the medical device review process.[2] [15],[3] [16]

The purpose of this guidance document is to identify: (1) the types of PMAs and BLAs subject to device user fees; (2) exceptions to user fees; and (3) the actions that may result in refunds of user fees that have been paid. This document incorporates the impact of process improvements from MDUFA III.

FDA's guidance documents, including this guidance document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is

suggested or recommended, but not required.

II. Types of PMA Applications Subject to User Fees[4] [17]

In accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by FDASIA, the following types of PMA applications[5] [18] are subject to user fees:

- Original PMAs;
- Modular PMAs;
- Premarket Reports;
- Licensing Agreement PMAs;
- Panel-Track Supplements;
- 180-day Supplements;
- Real-time Supplements;
- 30-day Notices; and
- Periodic Reports.

A. Original PMAs

An original PMA is one in which all elements required under 21 CFR 814.20 are submitted at the same time in a single application. For original PMAs submitted on or after October 1, 2002, FDA will assess the user fee in effect at the time of the submission (e.g., $248,000 in fiscal year 2013 (FY 13)).[6] [19]

B. Modular PMAs

A modular PMA is a compilation of sections or “modules” that are submitted at different times that together become a complete application.[7] [20] For modular PMAs submitted on or after October 1, 2002, FDA will assess the user fee in effect for an original PMA at the time of submission of the first module.[8] [21]

C. Premarket Reports

A Premarket Report (PMR) is a marketing application for Class III reprocessed single use devices (SUDs) that otherwise would have required a pre-market approval application.[9] [22] Among other information, a PMR must include validation data regarding cleaning, sterilization, and functional performance of the reprocessed device to ensure it is substantially equivalent to a legally marketed device. For PMRs submitted on or after October 1, 2002, FDA will assess the user fee in effect for an original PMA at the time of the submission.

D. Licensing Agreement PMAs

A licensing agreement PMA involves a PMA applicant (hereafter referred to as a licensor) entering into a licensing agreement with another party (hereafter referred to as a licensee) to provide that party with permission to reference the data in its

PMA. The licensee, after submitting the licensing agreement PMA to FDA, may request FDA to approve its own device, by referencing all the information that was used as a basis for approval of the licensor's device. Upon receiving FDA's approval, the licensee assumes all the responsibilities of a PMA applicant, including the manufacture and distribution of a device that is identical to the licensor's. In addition, following approval of the licensing agreement, licensees may choose to make changes to their product. As for all PMA applicants, such changes may require the submission of a PMA supplement.

Under the FD&C Act's user fee provisions, there is no distinction with respect to fee amounts for PMAs based on licensing agreements, and those based on original data.[10] [23] Therefore, original PMAs and PMA supplements based on licensing agreements are subject to the same fees as submissions based on original data. Similarly, certain PMA supplements submitted to a licensee's PMA would be subject to a user fee just as such supplements to a licensor's PMA would be subject to user fees.

E. Panel-Track Supplements

Section 737(4)(B) of the FD&C Act defines "panel-track supplement" as "supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness."[11] [24]

For panel-track supplements submitted on or after October 1, 2002, FDA will assess the user fee in effect at the time of submission (e.g., $186,000 for FY 13).[12] [25]

F. 180-Day Supplements

Section 737(4)(C) of the FD&C Act defines "180-day supplement" as "a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling."[13] [26]

For 180-day supplements submitted on or after October 1, 2002, FDA will assess the user fee in effect at the time of the submission (e.g., $37,200 for FY 13).[14] [27]

G. Real-Time Supplements

Section 737(4)(D) of the FD&C Act defines "real time supplement" as "a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement."[15] [28]

For real-time supplements submitted on or after October 1, 2002, FDA will assess

the user fee in effect at the time of the submission (e.g., $17,360 for FY 13).[16] [29]

H. 30-Day Notices

Section 737(5) of the FD&C Act defines “30-day notice” as “a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device."[17] [30]

For 30-day notices received on or after October 1, 2007, FDA will assess the user fee in effect at the time of the submission (e.g., $3,968 for FY 13).[18] [31] If a 30-day notice is converted to a 135-day supplement, the user fee paid for the 30-day notice will not be refunded.

I. Periodic Reports[19] [32]

Under section 212 of FDAAA, PMA applicants are subject to an “annual fee for periodic reporting concerning a class III device.” FDA will assess the user fee in effect at the time of the submission of the periodic report (e.g., $8,680 for FY 13).[20] [33],[21] [34] Devices with approved PMAs that have been subsequently reclassified into class II or withdrawn are not subject to PMA regulations and, therefore, will not be assessed a periodic reporting user fee. Although FDA has allowed some applicants to submit bundled periodic reports, the annual fee is required for each PMA identified in the periodic report.

III. Types of Biologics License Applications Subject to Device User Fees

In accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by FDASIA, the following applications for devices subject to licensure under section 351 of the PHS Act, are subject to user fees:

- Original biologics license applications (BLAs), which are included in the user fee definition of “premarket application” in section 737(1) of the FD&C Act;
- BLA Efficacy Supplements (BLSs), which are defined for user fee purposes in section 737(4)(E).

Under section 738(a)(2)(A)(i), (vii), both of these applications are assessed the user fee applicable to a premarket application that is in effect at the time of the submission (e.g., $248,000 in fiscal year 2013 (FY 13)).

A. Original BLAs

An original BLA is one in which all elements required under 21 CFR 601.2 are submitted at the same time in a single application.

B. A BLA Efficacy Supplement

According to section 737(4)(E) of the Act, “efficacy supplement” is defined as “a supplement to an approved premarket application under section 351 of the Public Health Service Act that requires substantive clinical data.”[22] [35]

IV. Exceptions to User Fees

Under the FD&C Act’s user fee provisions, any PMA or BLA that is intended solely for a pediatric population is exempt from user fees.[23] [36] There may be situations where, upon review of the device and its intended population, FDA determines that the application qualified for the pediatric exception although the applicant did not request a waiver. In such a case, FDA would refund the user fee. However, if after approval of an original or modular PMA or a BLA for pediatric use, the applicant proposes conditions of use for an adult population, the supplement is subject to the full user fee of a traditional PMA or BLA in effect at the time of submission.[24] [37]

A first ever original PMA or BLA submitted by a qualifying small business is also granted a one-time waiver of the user fee.[25] [38] To quality for this exception, a business (together with its affiliates) must have gross receipts or sales of no more than $30 million for the most recent tax year.[26] [39]

Additionally, a biologics license application submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only is exempt from user fees.[27] [40]

The FD&C Act also allows an exception from user fees for a PMA or BLA submitted by a state or federal government entity “unless the device involved is to be distributed commercially.”[28] [41] While permitted by statute, FDA does not anticipate that many PMAs or BLAs will be submitted under these circumstances.

V. User Fee Payments

As outlined below, there are three ways you may submit your user fee.[29] [42] Be sure to include the Payment Identification Number (PIN, beginning with MD)[30] [43] and the FDA P.O. Box on your check, bank draft, or U.S. Postal Money Order. Also, you should include a printed copy of your User Fee Cover Sheet (Form FDA-3601, accessible through FDA’s User Fee System [44] with your payment.

1) Preferred method: Credit Card or Electronic Check (ACH): FDA has partnered with the U.S. Department of the Treasury to utilize www.pay.gov [45], a Web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. To pay online, select the “Pay Now” button. Credit card transactions for cover sheets are limited to $5,000.

2) Check: All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Please write your unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover

sheet, on the check and mail the check to the appropriate address listed below. FDA will not be able to process your payment correctly without your cover sheet PIN.

Check Payments by mail:
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733
Note: In no case should payment be submitted with the application.

Check Payments delivered by a courier service:
US Bank
ATTN: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101
Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact the US Bank at (314) 418-4013.

3) Wire Transfer: Please include your application's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, in your wire transfer. Without the PIN your payment may not be applied to your cover sheet and review of your application will be delayed.

The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your cover sheet is fully paid.

Wire Transfer information:

New York Federal Reserve Bank
US Department of the Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045

FDA Deposit Account Number: 75060099
US Department of Treasury routing/transit number: 021030004
SWIFT Number: FRNYUS33
Beneficiary: FDA
1350 Piccard Drive
Rockville, MD 20850

VI. User Fee Refunds

User fee refunds are handled as described below.

A. eCopy criteria not met for a PMA Application

If FDA does not receive an eCopy,[31] [46] or receives an eCopy that cannot be accepted because it does not meet our technical standards, the omission or reasons for that failure will be communicated to the applicant in writing to aid in their creation of a valid replacement eCopy. If a valid eCopy is not received within 180 days of this notification, the submission will be deleted from our system and FDA will refund the fee paid.

B. Acceptance criteria not met for a PMA Application

If after an administrative review, FDA determines the required elements are not present in the PMA application, the applicant will be notified within 15 days of receipt in writing that the submission is incomplete and has not been accepted. If the applicant decides not to provide the missing information, they may send a letter to withdraw the submission and request a refund of the fee paid.

C. Applicant requests withdrawal of an Original PMA or Panel-Track Supplement before filing

If an applicant requests withdrawal of an original PMA or panel-track supplement before FDA makes the filing decision, we will refund 75% of the user fee.[32] [47]

D. Filing criteria not met for an Original PMA or Panel-Track Supplement

If FDA issues a not-filed letter for an original PMA or panel-track supplement, the applicant can request a refund of 75% of the fee paid.[33] [48] When an applicant amends a PMA to respond to a not-filed letter, FDA will require the full user fee in effect at the time of submission. For additional information, please refer to the Guidance for Industry and FDA Staff - Acceptance and Filing Review for Premarket Approval Applications (PMAs) [49], issued on December 31, 2012.

E. Applicant requests withdrawal of a filed Original PMA or Panel-Track Supplement, but FDA has not taken a first action

FDA has the discretion to refund fees if an applicant withdraws its PMA or panel-track supplement after FDA has filed it, but before we have taken a first action.[34] [50] First actions may be the issuance of a major deficiency letter, a not approvable letter, an approvable letter, an approval order, or a withdrawal letter.[35] [51]

FDA will base any refund it issues *after* a filing, but *before* a first action is taken, on the “level of effort already expended on the review,” as required by the FD&C Act.[36] [52] FDA believes that, in most instances, our level of effort can be appropriately assessed by the number of days that an application was under review. This approach permits FDA to calculate and process refunds much more efficiently than if we were to attempt to estimate factors on a case-by-case basis, such as the amount of time each member of the review team spent on the review and the significance and complexity of the scientific, medical, technical, and regulatory issues examined during the course of the review.

For these reasons, FDA intends to make refunds by referring to the following guidelines for original PMAs and panel-track supplements:

- when withdrawn between the date of the filing decision and day 90, a 50% refund of the user fee;
- when withdrawn between day 91 and day 135, a 25% refund of the user fee; or
- when withdrawn after day 135, no user fee refund.

FDA recognizes, however, that when there are unusual circumstances, the number of days that an application was under review may not provide a complete picture. Under such unusual circumstances, FDA may take additional factors other than the number of days under review into consideration.

Although you may request that FDA reconsider its decision about a user fee refund, “[t]he Secretary has sole discretion to refund a fee or portion of the fee” for an application withdrawn after filing but before first action.[37] [53] A determination by the Secretary concerning a refund is not reviewable.[38] [54]

F. FDA has taken a first action on an original PMA or Panel-Track Supplement

In accordance with the FD&C Act, if an applicant requests withdrawal of an original PMA or panel-track supplement at any time after FDA has taken its first action, regardless of when the action is taken, FDA will not refund any portion of the user fee.[39] [55]

G. Modular PMAs

For a modular PMA, the applicant is required by statute to pay a full fee for an original PMA when the first module is submitted.[40] [56] Although there is no filing review completed on the individual modules, actions can be taken. Module actions include an acceptance letter or a deficiency letter.

Upon receipt of the last module, the modular PMA is converted to an original PMA review track. At that point, the filing review for that PMA is initiated.[41] [57]

User fee refunds for modular PMAs for which the first module was received between October 1, 2002 and September 30, 2007 will be handled in the following manner:

- when withdrawn prior to FDA’s filing decision, a 75% refund of the user fee;[42] [58]
- when withdrawn after the filing decision but before a first action, FDA will follow the guidelines presented in Section IV, Part E above; or
- when withdrawn after the filing decision and a first action, no user fee refund.[43] [59]

User fee refunds for modular PMAs for which the first module was received on or after October 1, 2007 will be handled in the following manner:

- when withdrawn prior to submission of a second module and before a first action on the first module, a 75% refund of the user fee;[44] [60] or
- when withdrawn after a second or subsequent module is submitted but before any first action, the refund, if any, will be based on the "level of effort already expended on the review on the modules submitted."[45] [61]For this situation, FDA intends to make refunds by referring to the following guidelines:
    - after a second module but before any first action, 50% refund of the user fee;
    - after a third module but before any first action, 25% refund of the user fee; or
    - after a fourth or subsequent module, no user fee refund.

H. Premarket Reports

For premarket reports, FDA will follow the same user fee refund provisions as described above for original PMAs in parts C through F.

I. Licensing Agreement PMAs

Licensing Agreement PMAs are considered filed upon receipt. In cases where an applicant submits a licensing agreement PMA that includes new manufacturing procedures and/or a new manufacturing facility and requests withdrawal before FDA takes its first action, we intend to apply the refund policy discussed above (see Section IV., part E above) for original PMAs. If, however, the licensing agreement PMA incorporates by authorized reference all the information required by 21 CFR 814.20, including the same manufacturing procedures and facilities, and an applicant requests withdrawal before first action (generally an approval order), FDA plans to refund the full user fee.

J. 180-Day Supplements

For 180-day supplements, FDA considers the application filed upon receipt. The fees for these types of supplements are significantly less than those required for original PMAs, and, generally, the reviews are conducted over a shorter period of time. Therefore, in accordance with FDA's authority under section 738(a)(2)(D)(iii) of the FD&C Act, which bases the refund on the amount of effort expended, FDA does not intend to refund any amount of the user fee for this type of supplement after it has been filed.

K. Real-Time Supplements

For real-time supplements, FDA will follow the same user fee refund provisions as described above for 180-day supplements.

L. 30-Day Notices

For 30-day notices, FDA will follow the same user fee refund provisions as described above for 180-day supplements.

M. Periodic Reports

FDA does not intend to refund any amount of the annual fee for periodic reports.

N. eCopy criteria not met for a BLA Application

If FDA does not receive an eCopy,[31] [46] or receives an eCopy that cannot be accepted because it does not meet our technical requirements, the omission or reasons for that failure will be communicated to the applicant in writing to aid in their creation of a valid replacement eCopy. If a valid eCopy is not received within 180 days of this notification, the submission will be deleted from our system and FDA will refund the fee paid.

O. Applicant requests withdrawal of an Original BLA or Efficacy Supplement before filing

If an applicant requests withdrawal of an original BLA or efficacy supplement before FDA makes the filing decision, we will refund 75% of the user fee.[46] [62]

P. Filing criteria not met for an Original BLA or Efficacy Supplement

If FDA issues a refusal to file letter for an original BLA or efficacy supplement, the applicant can request a refund of 75% of the fee paid.[47] [63] When an applicant resubmits a BLA in response to a refusal to file letter, FDA will require the full user fee in effect at the time of resubmission.

Q. Applicant requests withdrawal of a filed Original BLA or Efficacy Supplement, but FDA has not taken a first action

FDA has the discretion to refund fees if an applicant withdraws its BLA or efficacy supplement after FDA has filed it, but before we have taken a first action.[48] [64] First action means the issuance of a complete action letter after the complete review of a filed complete application.

FDA will base any refund it issues *after* a filing, but *before* a first action is taken, on the “level of effort already expended on the review,” as required by the FD&C Act.[49] [65] FDA believes that, in most instances, our level of effort can be appropriately assessed by the number of days that an application was under review. This approach permits FDA to calculate and process refunds much more efficiently than if we were to attempt to estimate factors on a case-by-case basis, such as the amount of time each member of the review team spent on the review and the significance and complexity of the scientific, medical, technical, and regulatory issues examined during the course of the review.

For these reasons, FDA intends to make refunds by referring to the following guidelines for original BLAs and efficacy supplements:

- when withdrawn between the date of the filing decision and day 152, a 50% refund of the user fee;
- when withdrawn between day 152 and day 228, a 25% refund of the user fee; or
- when withdrawn after day 228, no user fee refund.

FDA recognizes, however, that when there are unusual circumstances, the number of days that an application was under review may not provide a complete picture. Under such unusual circumstances, FDA may take additional factors other than the number of days under review into consideration.

Although you may request that FDA reconsider its decision about a user fee refund, "[t]he Secretary has sole discretion to refund a fee or portion of the fee" for an application withdrawn after filing but before first action.[50] [66] A determination by the Secretary concerning a refund is not reviewable.[51] [67]

R. FDA has taken a first action on an original BLA or Efficacy Supplement

In accordance with the FD&C Act, if an applicant requests withdrawal of an original BLA or efficacy supplement at any time after FDA has taken its first action, regardless of when the action is taken, FDA will not refund any portion of the user fee.[52] [68]

VII. How to Request a User Fee Refund

To request a refund, an applicant must submit a written request to the appropriate Center in FDA at the address below *no later than 180 days after the fee was due.*[53] [69]

For products regulated by CDRH:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66 – G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

For products regulated by CBER:

U.S. Food and Drug Administration
Document Control Center, HFM-99
Center for Biologics Evaluation and Research
Food and Drug Administration

1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448.

List of References

- For the most recent version of a guidance, check the CDRH Guidance Webpage [70]
- FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals Performance [71]
- Premarket Approval Application Modular Review [72]
- Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process [73]
- Real-Time Premarket Approval Application (PMA) Supplements [74]
- 30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes [75]
- Procedures for Handling Post-Approval Studies Imposed by PMA Order [76]
- Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products [77]
- Guidance for Industry and FDA Staff - Acceptance and Filing Review for Premarket Approval Applications (PMAs) [49]
- eCopy Program for Medical Device Submissions [78]
- Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA [79]

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[1]See the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA, Public Law 112-114).

[2]For more information on performance goals for PMAs, see the guidance "FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals Performance [71]," issued on October 15, 2012. Web addresses for all guidance documents referenced within this guidance can be found in the "List of References" at the end of this document.

[3]Performance goals established for BLAs are outlined in "MDUFA Performance Goals and Procedures [80]," (attachment to letter dated July 16, 2012 from Secretary of Health and Human Services Kathleen Sebelius to The Honorable Fred Upton, Chairman, U.S. House of Representatives Committee on Energy & Commerce).

[4]See Section 738(a)(2)(A) of the FD&C Act.

[5]Section 737(1) of the FD&C Act includes product development protocols within the definition of premarket applications subject to user fees.

[6]See section 738(b)(2) of the FD&C Act.

[7]For more information on the modular PMA process, see the guidance document entitled, "Premarket Approval Application Modular Review [72]," issued on

November 3, 2003.

[8]See section 738(a)(2)(C) of the FD&C Act.

[9]See section 515(c)(2)(A) of the FD&C Act.

[10]See section 738(a)(2)(A) of the FD&C Act.

[11]For more information on panel-track supplements, see the guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process [73]," issued on December 11, 2008.

[12]See section 738(a)(2)(A)(iii).

[13]For more information on 180-day supplements, see the guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process [73]" issued on December 11, 2008.

[14]See section 738(a)(2)(A)(iv) of the FD&C Act.

[15]For more information on real-time supplements, see the guidance document entitled, "Real-Time Premarket Approval Application (PMA) Supplements [74]," issued on April 28, 2006. In addition, see the guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process [73]," issued on December 11, 2008.

[16]See section 738(a)(2)(A)(v) of the FD&C Act.

[17]For more information on 30-day notices, see the guidance document entitled, "30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes [75]," issued on April 13, 2011. In addition, see the guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision-Making Process [73]," issued on December 11, 2008.

[18]See section 738(a)(2)(A)(vi) of the FD&C Act.

[19]In accordance with 21 CFR 814.82(a)(7), FDA may require, as a condition of approval, submission to FDA at intervals specified in the approval order of periodic reports containing the information required by 21 CFR 814.84(b). In most cases, after the PMA is approved, the PMA applicant is required to submit reports to FDA annually unless a different time frame is specified in the approval order. Accordingly, periodic reports are typically referred to by FDA and industry as "annual reports." Periodic reports are separate from the postapproval study reports, which are discussed in the guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order [76]," issued on June 15, 2009.

[20]See section 738(a)(2)(A)(x) of the FD&C Act.

[21]PMAs are not subject to the periodic reporting user fee until the first fiscal year

following approval of the original PMA. This corresponds to when the first periodic report would be due.

[22]For more information on efficacy supplements, see the guidance document entitled, "Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products [77]," issued on February 25, 2003.

[23]See section 738(a)(2)(B)(v)(I) of the FD&C Act.

[24]See section 738(a)(2)(B)(v)(II) of the FD&C Act.

[25]See section 738(d)(1) of the FD&C Act.

[26]See section 738(d)(1) of the FD&C Act.

[27]See section 738(a)(2)(B)(ii) of the FD&C Act.

[28]See section 738(a)(2)(B)(iii) of the FD&C Act.

[29]Additional information regarding payment of user fees is available at https://userfees.fda.gov/OA_HTML/mdufmaFAQ.html [81]

[30]A PIN is obtained after creating a User Fee Cover Sheet and selecting "Submit Cover Sheet to FDA."

[31]FDA has issued guidance entitled, "eCopy Program for Medical Device Submissions [78]," issued on December 31, 2012, to implement section 1136 of FDASIA, which added Section 745A(b) of the FD&C Act, and provides statutory authority to require eCopy.

[32]See section 738(a)(2)(D)(ii) of the FD&C Act.

[33]See section 738(a)(2)(D)(i) of the FD&C Act.

[34]See section 738(a)(2)(D)(iii) of the FD&C Act.

[35]See the guidance document entitled, "FDA and Industry Actions of Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Performance Assessment [71]."

[36]See section 738(a)(2)(D)(iii) of the FD&C Act.

[37]Section 738(a)(2)(D)(vi) of the FD&C Act.

[38]Id. See the guidance document entitled, "Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA [79]," issued on November 17, 2004.

[39]Section 738(a)(2)(D)(iii) of the FD&C Act does not provide FDA with authority to refund any portion of fees after the agency has taken a first action on an application.

[40]See section 738(a)(2)(C) of the FD&C Act.

[41]See the guidance document entitled, "Premarket Approval Application Modular Review [82]," issued on November 3, 2003, for a complete discussion of the modular PMA review program. As detailed in this guidance document, the last module generally is the clinical module, and FDA bases its filing decision on this last module.

[42]See section 738(a)(2)(D)(ii) of the FD&C Act.

[43]See section 738(a)(2)(D)(iii) of the FD&C Act.

[44]See section 738(a)(2)(D)(iv) of the FD&C Act.

[45]See section 738(a)(2)(D)(v) of the FD&C Act.

[46]See section 738(a)(2)(D)(ii) of the FD&C Act.

[47]See section 738(a)(2)(D)(i) of the FD&C Act.

[48]See section 738(a)(2)(D)(iii) of the FD&C Act.

[49]See section 738(a)(2)(D)(iii) of the FD&C Act.

[50]Section 738(a)(2)(D)(vi) of the FD&C Act.

[51]Id. See the guidance document entitled, "Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA [79]," issued on November 17, 2004.

[52]Section 738(a)(2)(D)(iii) of the FD&C Act does not provide FDA with authority to refund any portion of fees after the agency has taken a first action on an application.

[53]See section 738(j) of the FD&C Act.

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[70] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
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[73] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm
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cuments/ucm089602.htm
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