Guidance for
Industry and FDA Staff

Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA

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

Contains Nonbinding Recommendations

Table of Contents

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to —

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD, 20852

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance, contact —

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Center for Biologics Evaluation and Research (HFM-4)
Food and Drug Administration
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Rockville, MD 20852-1448
Telephone: (301) 827-0379

– or –

Les S. Weinstein, CDRH Ombudsman
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Additional Copies

Additional copies are available from the Internet at:
www.fda.gov/cdrh/mdufma/guidance/1303.pdf

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The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that the information requested in the guidance is not relevant to the decision-making process or that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at —

www.fda.gov/cdrh/resolvingdisputes/ombudsman.html

Contains Nonbinding Recommendations

Guidance for
Industry and FDA Staff

Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA

I. Background

This guidance provides FDA's recommendations concerning the most timely and effective way to resolve disputes concerning FDA actions that affect the payment or refund of a user fee assessed under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). In some instances, alternative appeals processes may be available.

Full information on appeals processes used by the Center for Devices and Radiological Health (CDRH) is provided in —

- *Medical Device Appeals and Complaints: Guidance on Dispute Resolution* (February 1998). This guidance provides general information on the dispute resolution processes used by CDRH, including alternatives to the approaches recommended by this guidance.

- *A Suggested Approach to Resolving Least Burdensome Issues* (September 2000). This guidance provides information on how to resolve questions concerning whether an FDA request for information is the least burdensome means of addressing a regulatory issue.

- *Resolving Scientific Disputes Concerning the Regulation of Medical Devices — A Guide to Use of the Medical Devices Dispute Resolution Panel* (July 2001). FDA does not expect this guidance to apply to any dispute concerning a medical device user fee.

These CDRH guidance documents are available at —

www.fda.gov/cdrh/ombudsman/dispute.html

Full information on appeals processes used by the Center for Biologics Evaluation and Research (CBER) is provided in —

- SOPP 8005, *Major Dispute Resolution Process* (February 1999) is available at —

  www.fda.gov/cber/regsopp/8005.htm

- SOPP 8404, *Refusal to File Guidance for Product License Applications and Establishment License Applications* (October 2002) is available at —

  www.fda.gov/cber/regsopp/8404.htm

Note concerning statutory citations. Throughout this document, all statutory citations are to the Federal Food, Drug, and Cosmetic Act except where otherwise noted.

II. Internal Review through the Supervisory Chain

In most instances, FDA believes disputes in the areas covered by this guidance are best resolved through a request for internal review through the supervisory chain under 21 C.F.R. § 10.75. A review through the supervisory chain is an informal process that is usually far more timely than any other review option. For this reason, we are providing an overview of this important process. For additional information, see the regulation itself and the other references cited throughout this guidance.

Most disputes concerning actions that affect the payment or refund of a MDUFMA fee will involve a specific application or submission. The remaining disputes will concern whether an applicant qualifies as a small business or government entity. FDA does not expect such disputes to involve scientific issues. This overview is written from that perspective.

Overview of 21 C.F.R. § 10.75 as it relates to MDUFMA fees. Upon request of the applicant, an FDA decision concerning an application may generally be reviewed by the supervisor of the employee who made the decision. A review under 21 C.F.R. § 10.75 will ordinarily follow the established FDA supervisory or review chain. The review will involve consultation between the supervisor and the employee, or review of the administrative file by the supervisor. The applicant does not participate in the review. In most instances, a review will be completed at a supervisory level below the Center Director or the Office of the Commissioner.

Alternative approaches. In all but the most unusual circumstances, an internal review through the supervisory chain can be requested, granted, and completed in far less time than other dispute resolution processes provided by FDA regulations. Depending on the particular circumstances, alternatives include a citizen petition (21 C.F.R. § 10.30), administrative reconsideration of an action (21 C.F.R. § 10.33), a formal evidentiary public hearing (21 C.F.R. Part 12), a public hearing before a board of inquiry (21 C.F.R. Part 13), a public hearing before a public advisory committee (21 C.F.R. Part 14), a public hearing before the FDA Commissioner (21 C.F.R. Part 15), and a regulatory hearing before the Food and Drug Administration (21 C.F.R. Part 16). See the guidance documents listed in the *Background* section (p.) for information on these alternative approaches.

III. Recommended Procedures for Resolving Disputes that Affect the Payment or Refund of Medical Device User Fees

Questions Concerning the Amount of a Fee or Refund

1. Can I negotiate or appeal the *amount* of a fee FDA wants me to pay or the *amount* of a refund FDA wants to pay to me?

You cannot appeal the *amount* of a fee or the *amount* of a refund. You *can* appeal the *FDA action* that requires you to pay a particular fee or that will result in a particular refund.

Fee amounts. The fee amounts FDA assesses under MDUFMA are set by FDA each year. We follow instructions provided by law when we set these fees. We announce updated fees for the next fiscal year by August 2 of each year, and we publish those fees in a *Federal Register* notice. *See* sections 738(a)(1)(A) and 738(c). Every applicant who must pay a MDUFMA fee must pay the published fee that applies to any application it submits.

MDUFMA provides several fee exemptions and waivers and provides for lower fees when an applicant has qualified as a "small business," but MDUFMA does not authorize FDA to negotiate the amount of a fee to be paid for a particular application or to waive or reduce a fee simply because the fee would present a financial hardship to a particular applicant. We can provide a fee waiver or reduction only when the law specifically provides us the authority to do so.

Refunds. FDA will <u>not refund</u> any portion of a MDUFMA review fee —

- after we have accepted your 510(k) premarket notification;
- after we have accepted your 180-day PMA supplement;
- after we have accepted your real-time PMA supplement;
- after we have taken a first action on your application.

See question 14, p. , for additional information on these restrictions on refunds.

In other circumstances, a refund is possible. MDUFMA specifically provides for a refund if FDA refuses to file your application or if you withdraw your application within time frames set by the law.

The law requires FDA to refund 75% of a fee if we refuse to file your application or you withdraw your application before we make a filing decision. *See* sections 738(a)(1)(D)(i) and 738(a)(1)(D)(ii).

If you withdraw your application *after* we make a filing decision but *before* we take a *first action*, the law gives FDA "sole discretion" to refund "some or all" of the fee "based on the level of effort already expended on the review." Section 738(a)(1)(D)(iii). 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. We have issued guidance explaining how we generally intend to make a refund in such situations for traditional premarket approval applications (PMAs) and panel-track PMA supplements; see *User Fees and Refunds for Premarket Approval Applications*, available at

www.fda.gov/cdrh/mdufma/guidance/1224.pdf.

That guidance explains that, unless there are unusual circumstances, we will normally provide such refunds as follows:

Refund Normally to be Provided when a PMA or Panel-track PMA Supplement is Withdrawn by the Applicant	
When Withdrawn (Days from Receipt)	**Normal Refund Amount**
Before filing	75%
After filing to day 90	50%
Between day 91 and day 135	25%
After day 135	No refund

There may be instances where our level of effort is not adequately reflected by looking at elapsed time alone. If that is the case, we may adjust the amount of your refund to reflect any special circumstances that apply.

If you withdraw your application *after* we make a filing decision but before we take a first action, *FDA's decision regarding whether to make a refund of any portion of the fee paid for review of that application, and the amount of any such refund, is not reviewable*. FDA will not consider any appeal, and you cannot obtain judicial review of FDA's decision. *See* section 738(a)(1)(D)(iii). For additional information on FDA "first actions," see question 14.

The law does not permit FDA to negotiate the amount of a refund for a particular application or to increase the amount of the refund to avoid a financial hardship to a particular applicant. The law does not permit FDA to give you a "credit" towards a future new application or resubmission of an application.

2. Will FDA review my application while I proceed with an appeal?

No. FDA cannot review your application if you pay less than the entire amount of any fee that applies. This is because the law requires FDA to consider your submission "incomplete" and it instructs us that the submission "shall not be accepted for filing . . . until all fees owed . . . have been paid." *See* section 738(f). If you want FDA to begin a review of your application while you appeal an FDA decision that requires you to pay a fee, you should pay the fee sought by FDA. If your appeal results in a determination that you should have paid a lower fee (or no fee), FDA will refund any excess payment you made.

Appeals Concerning an Applicant's Status

3. How can I appeal an FDA determination that I am not a "small business" under MDUFMA and must pay a full fee rather than a reduced or waived "small business" fee?

FDA uses information you provide on a Small Business Qualification Certification (Form FDA 3602) to determine whether you are a "small business" within the meaning of MDUFMA. This form, instructions, and an explanation of the criteria and process FDA will use to evaluate your information, are provided in an FDA guidance document that is updated each year. For FY 2005, see —

- *FY 2005 MDUFMA Small Business Qualification Worksheet and Certification* (available at www.fda.gov/cdrh/mdufma/guidance/2005.pdf).

To qualify as a small business for applications you submit during FY 2005, your "gross receipts and sales" — *including* the gross receipts and sales of *all* of your affiliates, partners, and parent firms — must be no more than $30 million. *See* sections 738(d)(2)(C) and 738(e)(2)(C). You must submit a completed Small Business Qualification Certification (Form FDA 3602) and copy of your most recent Federal (U.S.) income tax return for a taxable year to show that you qualify as a small business. FDA *cannot accept* a foreign tax return as a substitute for a Federal (U.S.) income tax return. *See* sections 738(d)(2)(B) and 738(e)(2)(B).

Each year, FDA will provide updated guidance on the criteria you must meet to qualify as a small business; this may include a revised "gross receipts and sales" threshold. We will publish this guidance around the time we publish the *Federal Register* notice

announcing MDUFMA fees for the next fiscal year (around August 2 of each year). The new guidance will be announced on our Internet site at www.fda.gov/cdrh/mdufma.

If FDA determines you are a small business, you will be eligible for reduced or waived MDUFMA user fees. *See* sections 738(d)(1) and 738(e)(1). If FDA determines you are not a small business, you must pay the full (standard) fee for an application that is subject to a fee.

The fee you must pay for an application is determined and fixed on the date FDA receives your application. *If you submit an application before FDA has determined you qualify as a small business, you must pay the standard (full) amount of any fee that applies.* FDA will not refund the difference between the standard (full) fee and the small business fee if you later qualify as a small business. *If you want to pay the small business fee for an application, do not submit the application until you obtain your Small Business Decision number from FDA.*

Examples of issues most likely to be presented on appeal:

- FDA may find that you did not disclose all of your affiliates, partners, and parent firms on your Small Business Qualification Certification. In this case, FDA will issue a determination that you are not a small business, but that we will consider a new Certification that discloses all omitted affiliates, partners, and parent firms. The inclusion of gross receipts or sales of an omitted affiliate, partner, or parent firm may take the applicant over the small business threshold ($30 million for FY 2004 and FY 2005). If you believe FDA's determination is incorrect, you may appeal our finding that a particular entity is an affiliate, partner, or parent firm.

- FDA could make a mathematical error in adding the gross receipts and sales you report for yourself and your affiliates, partners, and parent firms, with the error resulting in an FDA determination that you do not qualify as a small business. You may appeal an FDA determination that is based on such an error.

Recommended appeals process: You should request an internal review through the supervisory chain under 21 C.F.R. § 10.75. The review would proceed through:

- Initial request for reconsideration: Director, Division of Small Manufacturers, International, and Consumer Assistance.
- Appeal (follows reconsideration): Director, Office of Communication, Education, and Radiation Programs (OCER), CDRH. The decision of the Director, OCER, would be FDA's final decision.

FDA's final decision regarding whether an entity is a small business is not reviewable. FDA will not consider any subsequent appeal, and you cannot obtain judicial review of FDA's decision. *See* sections 738(d)(2)(D) and 738(e)(2)(D).

Recommended time frame for making your appeal: You should make your appeal within 60 days of FDA's determination that you are not a small business. FDA expects to respond to your appeal within 30 days.

Send your appeal to:

All appeals (both CBER and CDRH appeals) should be sent to:

MDUFMA Appeal
Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20850-4307

4. How can I appeal an FDA determination that I am not eligible for a fee waiver for an application submitted by a government entity?

FDA uses information you provide to determine —

- whether you are a "State or Federal Government entity" and
- whether your device is to be "distributed commercially."

If we determine you are a government entity *and* you will *not* commercially distribute your device, you will not have to pay a MDUFMA user fee for that application. *See* section 738(a)(1)(B)(iii). If you do not meet *both* criteria, you must pay any fee that applies to your application.

MDUFMA does not define "State or Federal Government entity." FDA administers another law, the Prescription Drug User Fee Act (PDUFA) that also exempts government entities from user fees for drug applications. This guidance uses the same definition of "State or Federal Government entity" that FDA is applying under PDUFA. Under this definition, you may qualify as a government entity by submitting a letter certifying that you meet *all* of the following criteria:

- You are an entity operated by a federal department, state, district, territory, possession, or federally-recognized Indian tribe.
- The entire salary of all of your personnel must be directly paid by a federal department, state, district, territory, possession, or federally-recognized Indian tribe.

- All of your equipment must be owned, rented by, or leased by a federal department, state, district, territory, possession, or federally-recognized Indian tribe.
- The ultimate authority to make day-to-day decisions concerning the management and operation of your business must come from a federal department, state, district, territory, possession, or federally-recognized Indian tribe.

Once we have determined you are a governmental entity, you may obtain a waiver of a MDUFMA fee for a particular application if you certify that you are a government entity and that you do not intend to commercially distribute the device for which you are requesting a fee waiver.

You will certify that you meet these requirements *each time* you submit an application for which you want a fee waiver. FDA will audit these certifications to ensure that applicants meet these criteria.

If we determine that you do not qualify as a government entity or if we determine that you will commercially distribute your device, we will send you a letter informing you of our determination and summarizing its basis.

Examples of issues most likely to be presented on appeal:

- FDA may determine you do not qualify as a government entity because you do not appear to be operated by, and subject to oversight of, a State or Federal government.
- FDA may determine that you intend to commercially distribute the device that is the subject of your application.

Recommended appeals process: You should request an internal review through the supervisory chain under 21 C.F.R. § 10.75. The review would proceed through:

- Initial request for reconsideration: Director, Division of Small Manufacturers, International, and Consumer Assistance.
- Appeal (follows reconsideration): Director, Office of Communication, Education, and Radiation Programs, CDRH. The decision of the Director, OCER, would be FDA's final decision.

Recommended time frame for making your appeal: You should make your appeal within 60 days of FDA's determination that you are not a government entity. If FDA has determined that you are a government entity, but has determined that your device is to be "distributed commercially," you should appeal within 60 days of FDA's determination that your device will be distributed commercially. FDA expects to respond to your appeal within 30 days.

Send your appeal to:

All appeals (both CBER and CDRH appeals) should be sent to:

MDUFMA Appeal
Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20850-4307

5. How can I appeal an FDA decision to "not file" my application?

If FDA decides to "not file" your application, we will not review your application. FDA will refund 75% of the fee you paid (unless you did not pay the correct amount, in which case, we will adjust your refund). If you resubmit the application, you must pay the entire fee that applies to the application. FDA will not give you a "credit" for the portion of the fee that we retained when we determined we could not file your prior application.

FDA uses the following criteria when making a PMA filing decision:

- FDA's regulation, 21 C.F.R. § 814.42 – Filing a PMA; and
- FDA's guidance document, *Premarket Approval Application Filing Review* (available at www.fda.gov/cdrh/ode/guidance/297.pdf).

For BLAs, we apply:

- FDA's regulation, 21 C.F.R. § 601.2 – Applications for biologics licenses; procedures for filing;
- SOPP 8404, *Refusal to File Guidance for Product License Applications and Establishment License Applications* (October 2002); and
- SOPP 8404.1, *Procedures for Filing an Application When the Applicant Protests a Refusal to File Action (File Over Protest)* (October 2002).

For 510(k)s:

- FDA does not make a filing decision on 510(k)s, so there can be no dispute concerning filing of a 510(k).

Examples of issues most likely to be presented on appeal:

- These disputes will concern whether your application meets FDA's minimum threshold requirements for filing. If your appeal succeeds, FDA will file your

application and begin a review as soon as you resubmit the 75% of the fee we previously refunded to you.

Recommended appeals processes: FDA has specific appeals processes for resolution of disputes concerning the filing of an application.

- PMA: The appeals process is established by regulation at 21 C.F.R. § 814.42(d)(2):

  > Request in writing within 10 working days of the date of receipt of the notice refusing to file the PMA, an informal conference with the Director of the Office of Device Evaluation to review FDA's decision not to file the PMA. FDA will hold the informal conference within 10 working days of its receipt of the request and will render its decision on filing within 5 working days after the informal conference. If, after the informal conference, FDA accepts the PMA for filing, the date of filing will be the date of the decision to accept the PMA for filing. If FDA does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Director of the Center for Devices and Radiological Health. The Director's decision will constitute final administrative action for the purpose of judicial review.

- BLA: Appeals will follow the process described by SOPP 8005, *Major Dispute Resolution Process* (February 1999), and SOPP 8404.1, *Procedures for Filing an Application When the Applicant Protests a Refusal to File Action (File Over Protest)* (October 2002).

- 510(k): MDUFMA does not authorize a refund of any portion of a fee paid for a 510(k) that is withdrawn, and FDA will not grant a refund once a 510(k) fee has been paid and the 510(k) has been received. See FDA's guidance document, *User Fees and Refunds for Premarket Notification Submissions (510(k)s)*, available at —

  www.fda.gov/cdrh/mdufma/guidance/1511.pdf

  Because FDA will not provide a refund when a 510(k) is withdrawn, there is no appeals process.

Recommended time frame for making your appeal:

- PMA: You should make your appeal within "10 working days of the date of receipt of the notice refusing to file the PMA." *See* 21 C.F.R. § 814.42(d)(2). FDA expects to provide its decision "within 5 working days after the informal conference" that results from your appeal. *Id.*

- BLA: You should request a meeting within 30 days of notification of FDA's refusal to file the application. If we still refuse to file your application, you have 30 days to submit a written request that your application be filed over protest;

the normal standard or priority review clock will resume when we receive your request.

Send your appeal to:

CBER filing appeals: (Send your appeal to the office that refused to file your application.)

Director, Office of Blood Research and Review, HFM-300
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

or

Director, Office of Cell, Tissue, and Gene Therapies, HFM-700
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

CDRH filing appeals:

PMA filing appeals:

Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20857

6. How can I appeal an FDA determination that I must pay a higher fee because my submission is not the type of application I believe it to be?

If FDA determines —

- your submission is not the type of application you claimed, *and*
- the application type FDA determines it to be requires a higher fee than you paid,

then FDA will not accept your application until you pay the higher fee. This is because under the law your submission "shall be considered incomplete and shall not be accepted . . . until all fees owed . . . have been paid." *See* section 738(f).

In such instances, we will fax or mail you a letter (usually within one day) explaining that FDA will not file your submission unless you pay the appropriate fee within 30 days. If you do not pay the appropriate fee within 30 days, FDA will send you a letter explaining that the submission was not accepted, that FDA did not review the submission, and that the device may not be marketed until your obtain FDA clearance or approval. We will also refund any payment you made for review of the submission.

Examples of issues most likely to be presented on appeal:

- FDA determined that an application submitted as a 180-day PMA supplement must be reviewed as a panel-track supplement or as a PMA.
- FDA determined that an application submitted as a real-time PMA supplement must be reviewed as a 180-day supplement.
- FDA determined that an application submitted as a 30-day notice must be reviewed as a real-time supplement or a 180-day supplement.
- FDA determined that an application submitted as a BLA supplement for further manufacturing use must be reviewed as a BLA efficacy supplement or as a BLA.

Recommended appeals process: Internal review through the supervisory chain under 21 C.F.R. § 10.75

If FDA determined your application is to be reviewed by CDRH and is a PMA, a panel-track PMA supplement, a180-day PMA supplement, or a real-time supplement, your appeal through the supervisory chain would proceed through:

- Initial request for reconsideration: Director, Program Operations Staff, ODE, CDRH.
- Appeal (follows reconsideration): Director, Office of Device Evaluation, CDRH *or* Director, Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH. (Appeal will be made through the Office that is responsible for regulating your device.)

If FDA determines your application is to be reviewed by CBER and is a PMA, a panel-track supplement, a 180-day supplement, a real-time supplement, a BLA, or a BLA efficacy supplement, your appeal will follow the process described by SOPP 8005, *Major Dispute Resolution Process* (February 1999).

Recommended time frame for making your appeal: You should make your appeal within 30 days of FDA's decision that your application is a type of application that requires a higher fee than you paid. (*Note*: FDA will delete your application 30 days after we inform you of our decision that we cannot review it unless you pay the higher fee we have determined is due; if we delete your application, we will refund the full amount you paid for review of that submission.) FDA expects to respond to your appeal within 30 days.

Send your appeal to:

CBER appeals: (Send your appeal to the office that would review your application.)

Director, Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

or

Director, Office of Cell, Tissue, and Gene Therapies (HFM-700)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

CDRH appeals:

Director, Program Operations Staff (HFZ-402)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20857

7. How can I appeal an FDA determination that its review of my application had reached a particular stage when I withdrew the application?

The stage at which a review is terminated when you withdraw an application determines the amount of the fee FDA will refund:

- FDA will refund 75% of the fee if you withdraw your application *before* FDA files the application. Section 738(a)(1)(D)(ii).
- If FDA has filed your application, but has not yet taken a first action, FDA has "sole discretion" to refund "some or all" of the fee "based on the level of effort already expended on the review." Section 738(a)(1)(D)(iii). The answer to question 1, p. , provides information on the amount of the refund you can expect.

If you want a refund when you withdraw your application, you must make a "written request" for a refund "not later than 180 days after such fee is due." Section 738(j). All fees are due at the time the application is filed or accepted. *See* section 738(f). This means your request for a refund must be made within 180 days of the date FDA filed or accepted your application. If you do not request a refund when you withdraw your application, or you delay too long in making your request, FDA will not provide any refund.

The law does not authorize any refund of a 510(k) fee after FDA files the application. *See* section 738(a)(1)(D)(iii). Also, FDA has determined that we will not provide any refund —

- after we have accepted your 180-day PMA supplement; or
- after we have accepted your real-time PMA supplement.

FDA considers your 180-day or real-time PMA supplement to be filed as soon as we have received your supplement *and* you have paid the fee due for the review. Under section 738(a)(1)(D)(iii), after FDA has filed an application, we are to base any refund on the level of effort we expended. Because the fees for these supplements are much lower than the fee for an original premarket application and because these reviews are conducted under a shorter period of time, we have determined that the level of effort required to review these supplements is so significant that any refund would be unwarranted.

Examples of issues most likely to be presented on appeal:

- When did FDA receive notice that the applicant was withdrawing the application?
- Did FDA file the application prior to receiving notice that the applicant was withdrawing the application?
- Did FDA take a first action prior to receiving notice that the applicant was withdrawing the application?

Recommended appeals process: Internal review through the supervisory chain pursuant to 21 C.F.R. § 10.75.

Appeals through the CDRH supervisory chain would proceed through:

- Initial request for reconsideration: Chief, Premarket Approval Section, Program Operations Staff, ODE, CDRH.
- Appeal (follows reconsideration): Director, Program Operations Staff, ODE, CDRH.
- Final decision (follows appeal): Director, Office of Device Evaluation, CDRH *or* Director, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), CDRH. (Appeal will be made through the Office that is responsible for regulating your device.). The ODE or OIVD Director's decision would constitute final administrative action concerning the stage of review your application was at when you withdrew it, and the time at which the review was terminated. FDA's decision concerning the *amount* of any refund to be provided *after* a first action "shall not be reviewable." Section 738(a)(1)(D)(iii).

Appeals through the CBER supervisory chain will follow the process described by SOPP 8005, *Major Dispute Resolution Process* (February 1999), and would proceed through:

- Director, Office of Blood Research and Review
  or
  Director, Office of Cell, Tissue, and Gene Therapies
- Deputy Center Director, CBER
- Center Director, CBER

If FDA has filed your application, but has not yet taken a first action, FDA has "sole discretion" to refund "some or all" of the fee you paid "based on the level of effort already expended on the review." Section 738(a)(1)(D)(iii). In most instances, FDA believes our level of effort can be appropriately estimated by determining how much time has elapsed since we filed the application. There may be instances where our level of effort is not adequately reflected by looking at elapsed time alone, and our refund will reflect any special circumstances that apply. We will normally provide refunds as follows:

Refund Normally to be Provided when a PMA or Panel-track PMA Supplement is Withdrawn by the Applicant	
When Withdrawn (Days from Receipt)	**Normal Refund Amount**
Before filing	75%
After filing to day 90	50%
Between day 91 and day 135	25%
After day 135	No refund

See question 1 for additional information.

Whenever an application is withdrawn *after* filing but *before* a first action, *FDA's decision regarding whether to make a refund of any portion of the fee paid for review of that application, and the amount of any such refund, is* <u>*not reviewable*</u>. FDA will not consider any appeal, and you cannot obtain judicial review of FDA's decision. *See* section 738(a)(1)(D)(iii).

FDA has no authority to make any refund after we have taken a first action. *See* section 738(a)(1)(D).

Recommended time frame for making your appeal: You should make your appeal within 60 days of FDA's refund decision. FDA expects to respond to your appeal within 30 days.

Send your appeal to:

CBER appeals: (Send your appeal to the office that was reviewing your application.)

Director, Office of Blood Research and Review, HFM-300
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

or

Director, Office of Cell, Tissue, and Gene Therapies, HFM-700
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

CDRH appeals:

Chief, Premarket Approval Section (HFZ-402)
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20857

8. How can I appeal an FDA determination that a premarket application I submitted is *not* my first?

Section 738(d)(1) provides FDA "shall grant a waiver of the fee required . . . for one premarket application, or one premarket report, where . . . the applicant involved is a small business submitting its first premarket application . . . or its first premarket report . . . for review."

This discussion assumes FDA has already found that you are a "small business" (only a "small business" can obtain a waiver of the fee for its first PMA or first PMR). If that is not the case, see question 3.

Examples of issues most likely to be presented on appeal:

- If you are requesting a waiver for your first premarket application (PMA, PDP, PMR, or BLA), FDA may determine that you previously submitted a premarket application.[1]
- FDA may determine that one of your affiliates, partners, or parent firms previously submitted a premarket application.

Recommended appeals process: Internal review through the supervisory chain pursuant to 21 C.F.R. § 10.75

Appeals through the CDRH supervisory chain would proceed through:

- Initial request for reconsideration: Director, Program Operations Staff, ODE
- Appeal (follows reconsideration): Director, Office of Device Evaluation, CDRH *or* Director, Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH. (Appeal will be made through the Office that is responsible for regulating your device.) The ODE or OIVD Director's decision would constitute final administrative action.

Appeals through the CBER supervisory chain will follow the process described by SOPP 8005, *Major Dispute Resolution Process* (February 1999), beginning with the Director of the Office that was reviewing your application.

Special considerations: Only a *small business* is eligible for a fee waiver for its first premarket application under section 738(d)(1). To qualify for this waiver, you must establish your status as a small business *before* you submit your first premarket application. If you have not qualified as a small business at the time you submit your application, you must pay the full fee for that application.

Recommended time frame for making your appeal: You should make your appeal within 60 days of FDA's determination that a premarket application you submitted is not your first. FDA expects to respond to your appeal within 30 days.

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[1] If you are requesting a waiver for your *first* premarket report (PMR) for a reprocessed single-use device and you submitted a premarket approval application (PMA), *for the same device* prior to October 1, 2002, you may still obtain a fee waiver for that PMR. *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 an applicant who previously submitted a PMA for a reprocessed device, but who must submit a new application to satisfy requirements added by MDUFMA.

Send your appeal to:

CBER appeals:

Director, Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

or

Director, Office of Cell, Tissue, and Gene Therapies (HFM-700)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

CDRH appeals:

Director, Program Operations Staff (HFZ-402)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20857

9. How can I appeal FDA's designation of the primary review process for my combination product?

FDA's Office of Combination Products (OCP) assigns the review responsibility for a combination product based on the product's "primary mode of action." Section 503(g)(1).

You may obtain an FDA determination concerning your combination product's primary mode of action by submitting a "Request for Designation" (RFD) to OCP. OCP will make a determination within 60 days. The RFD process is outlined in 21 C.F.R. Part 3; 21 C.F.R. § 3.7 outlines the information we require in your RFD submission.

When OCP determines the primary mode of action of your product, that action will also determine how FDA will review and regulate your product. For example, when OCP determines that primary mode of action results from a drug component, that product will be reviewed and regulated as a drug by the Center for Drug Evaluation and Research. The primary review process may be subject to a user fee, either under MDUFMA or the Prescription Drug User Fee Act (PDUFA). PDUFA fees are higher than fees under MDUFMA, and may include both an application fee *and* annual product and establishment fees.

Criteria: The term *combination product* is defined at 21 C.F.R. § 3.2(e):

> *Combination product* includes:
>
> (1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
>
> (2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
>
> (3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
>
> (4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The Office of Combination Products assigns primary jurisdiction for a combination product to a particular Center based on the "primary mode of action" of the product. In making its determination, OCP refers to —

- Intercenter agreements relating to the review of combination products;
- *Regulation of Combination Products: FDA Employee Perspectives* (October 2002); and
- *Manual of Standard Operating Procedures and Policies – General Information – Review: Intercenter Consultative/Collaborative Review Process* (Version 2, February 14, 2003).

FDA has published a proposed rule, *Definition of Primary Mode of Action for a Combination Product*, 69 F.R. 25527 (May 7, 2004), but has not yet published a final rule. If a final rule goes into effect, it will provide the criteria FDA will use to determine primary mode of action. The proposed rule is available at www.fda.gov/OHRMS/DOCKETS/98fr/04-10447.pdf. OCP will provide additional information on its Internet site, www.fda.gov/oc/combination.

Examples of issues most likely to be presented on appeal:

- An FDA determination that an application for a combination product is to be regulated primarily as a human drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act rather than as a device regulated under section 515 or section 510(k) of the FD&C Act or under section 351 of the Public Health Service Act.

Recommended appeals process: Internal review through the supervisory chain pursuant to 21 C.F.R. § 10.75

All appeals will proceed through:

- Initial request for reconsideration: Director, Office of Combination Products, Office of the Commissioner.
- Appeal: (follows reconsideration): Principal Associate Commissioner, FDA.

Recommended time frame for making your appeal: You should make your appeal before you submit your application to FDA. FDA expects to respond to your appeal within 30 days.

Send your appeal to:

Director, Office of Combination Products (HF-7)
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

10. What can I do if FDA does not review and act on my combination product application in a timely manner?

If an issue remains unresolved after working with the lead Center, FDA's Office of Combination Products (OCP) can help facilitate a resolution of the issue. OCP has published a draft guidance document that provides additional information and explains how OCP can help. See *Combination Products — Timeliness of Premarket Reviews — Dispute Resolution Guidance*, available at www.fda.gov/oc/combination/dispute.pdf.

11. How can I appeal an FDA determination that I cannot "bundle" a device into a single application involving multiple devices? How can I appeal an FDA determination that I cannot "bundle" an indication for use of a device into a single application involving multiple indications for use for that device?

The extent to which bundling is, or is not, permitted in a particular case will determine whether the applicant pays a fee for a single application, or multiple fees for multiple applications.

All bundled devices should be within a generic type of device, and it should be possible for FDA to efficiently address all issues during the course of one review.

Before you submit a bundled application to FDA, you should review FDA's guidance, *Bundling Multiple Devices or Multiple Indications in a Single Submission*, available at —

www.fda.gov/cdrh/mdufma/guidance/1215.pdf

If you are unsure whether bundling is appropriate in your circumstances, you should contact FDA before you make your submission.

Examples of issues most likely to be presented on appeal:

- Are bundled devices within a generic type of device, and do they present issues that can be efficiently addressed during the course of one review?
- Are the indications for use desired by applicant sufficiently related that they can all be efficiently addressed during the course of one review?

Recommended appeals process: Internal review through the supervisory chain pursuant to 21 C.F.R. § 10.75

Appeals through the CDRH supervisory chain would proceed through:

- Initial request for reconsideration: Director, Program Operations Staff, ODE
- Appeal (follows reconsideration): Director, Office of Device Evaluation, CDRH *or* Director, Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH. (Appeal will be made through the Office that is responsible for regulating your device.)

Appeals through the CBER supervisory chain will follow the process described by SOPP 8005, *Major Dispute Resolution Process* (February 1999), beginning with the Director of the Office that was reviewing your application:

- Initial request for reconsideration:
  - — Director, Office of Blood Research and Review, *or*
  - — Director, Office of Cell, Tissue, and Gene Therapies
- Appeal (follows reconsideration): Deputy Center Director, CBER

Recommended time frame for making your appeal: FDA expects to respond to your appeal within 30 days.

Send your appeal to:

CBER appeals (send your appeal to the Office that would review your application):

Director, Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

or

Director, Office of Cell, Tissue, and Gene Therapies (HFM-700)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

CDRH appeals:

Director, Program Operations Staff (HFZ-402)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20857

12. How can I appeal an FDA determination that my application is *not* solely for a pediatric population?

Under section 738(a)(1)(B)(v)(I), FDA does not assess a fee for any application, or any supplement to an application, that is intended *solely* for a pediatric population. If your application includes an indication for any adult use, you must pay the fee that would normally apply to your application.

If you obtained a fee waiver for your *original* premarket application (PMA, PDP, PMR, or BLA) because it was intended solely for a pediatric population, and you later submit a *supplement* that proposes an adult condition of use, you will be required to pay the fee that would apply to an *original application* rather than the lower fee that would normally apply to your supplement. *See* section 738(a)(1)(B)(v)(II).

FDA cannot confirm your claim that an application is limited to pediatric indications until the application is filed and we have made significant progress in our review of the application. If, during our review, we identify a proposed adult use in an original application you claim is intended solely for a pediatric population, we will put your application on hold and suspend our review because under section 738(f) your application "shall be considered incomplete . . . until all fees owed . . . have been paid." We will inform you your application is on hold, usually within a day. We will not resume

our review until you pay the appropriate fee, or you remove the proposed adult use from your application, or an appeal determines there is no proposed adult use.

Similarly, if you obtained a fee waiver for your original application because it was represented as solely for a pediatric population, and we identify a proposed adult use in a later *supplement* to that application, and you did not include payment for an *original* application, we will put your application on hold and suspend our review, because under section 738(a)(1)(B)(v)(II) you must pay that higher fee and under section 738(f) your application "shall be considered incomplete . . . until all fees owed . . . have been paid." We will inform you your application is on hold, usually within a day. We will not resume our review until you pay the appropriate fee, or you remove the proposed adult use from your supplement, or an appeal determines there is no proposed adult use.

Examples of issues most likely to be presented on appeal:

- Is there any indication for an adult use?

Recommended appeals process: Internal review through the supervisory chain pursuant to 21 C.F.R. 10.75 —

Appeals through the CDRH supervisory chain would proceed through:

- Initial request for reconsideration: Director, Program Operations Staff, ODE
- Appeal (follows reconsideration): Director, Office of Device Evaluation, CDRH *or* Director, Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH. (Appeal will be made through the Office that is responsible for regulating your device.)

Appeals through the CBER supervisory chain will follow the process described by SOPP 8005, *Major Dispute Resolution Process* (February 1999), beginning with the Director of the Office that was reviewing your application.

- Initial request for reconsideration:
  — Director, Office of Blood Research and Review, *or*
  — Director, Office of Cell, Tissue, and Gene Therapies
- Appeals (follows reconsideration): Deputy Center Director, CBER

Recommended time frame for making your appeal: You should make your appeal within 60 days of FDA's determination that your application includes an indication for an adult use. FDA expects to respond to your appeal within 30 days.

Send your appeal to:

CBER appeals: (Send your appeal to the office that was reviewing your application.)

Director, Office of Blood Research and Review, HFM-300
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

or

Director, Office of Cell, Tissue, and Gene Therapies, HFM-700
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

CDRH appeals:

Director, Program Operations Staff (HFZ-402)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, MD 20857

13. I accidentally submitted a duplicate (second) payment for my application. Can I obtain a refund of the extra amount I paid?

Yes. FDA will grant all requests for refund of any portion of a payment that exceeds the correct fee for your application. Submit written documentation of your duplicate payment to the Center that received your application:

CDRH:

Financial Management Branch (HFZ-30)
Division of Planning, Analysis, and Finance
Office of Systems and Management
2098 Gaither Rd.
Rockville, MD 20857

CBER:

Regulatory Information Management Staff (HFM-110)
Office of Management
Center for Biologics Evaluation and Research
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448

14. I paid a fee for review of a 510(k), and FDA determined that my device is exempt from the requirement for a 510(k) premarket notification, *or* I paid a fee for review of a 510(k) or a PMA, and FDA determined that my product is not a device. Can I obtain a refund of the amount I paid?

Yes. FDA will automatically refund the fee you paid whenever we determine that our classification regulation exempts your device from the requirement to submit a premarket notification, or we determine your product is not a device. For additional information, see our guidance documents —

- *User Fees and Refunds for Premarket Notification Submissions (510(k)s)*, available at www.fda.gov/cdrh/mdufma/guidance/1511.pdf.

- *User Fees and Refunds for Premarket Approval Applications*, available at www.fda.gov/cdrh/mdufma/guidance/1224.pdf.

15. Are there instances where I cannot obtain a refund of any portion of a fee I have paid for review of a medical device application?

FDA will *not* refund any portion of a fee you paid if any one or more of the following situations —

- after we have accepted your 510(k) premarket notification;
- after we have accepted your 180-day PMA supplement;
- after we have accepted your real-time PMA supplement;
- after we have taken a *first action* on your application.

No refund after we have accepted your 510(k) premarket notification. MDUFMA does not authorize a refund of any portion of a fee paid for a 510(k) that is withdrawn, and FDA will not grant a refund once a 510(k) fee has been paid and the 510(k) has been received. See FDA's guidance document, *User Fees and Refunds for Premarket Notification Submissions (510(k)s)*, available at www.fda.gov/cdrh/mdufma/guidance/1511.pdf.

No refund after we have accepted your 180-day PMA supplement or your real-time PMA supplement. FDA considers your 180-day or real-time PMA supplement to be filed as soon as we have received your supplement *and* you have paid the fee due for the review. Under section 738(a)(1)(D)(iii), after FDA has filed an application, we are to base any refund on the level of effort we expended. Because the fees for these supplements are much lower than the fee for an original premarket application and because these reviews are conducted under a shorter period of time, we

have determined that the level of effort required to review these supplements is so significant that any refund would be unwarranted.

For additional information, see FDA's guidance, *User Fees and Refunds for Premarket Approval Applications*, available at www.fda.gov/cdrh/mdufma/guidance/1224.pdf.

No refund following a first action on your application. Under section 738(a)(1)(D), FDA does not have authority to grant a refund of any portion of a MDUFMA fee payment after we taken a first action. FDA will deny any request for a refund after we take a first action, and we will deny any appeal that requests a refund after a first action.

- *For an original PMA, PDP, PMR, or a panel-track PMA supplement*, a first action may be any of the following actions: approval, approvable, approvable pending good manufacturing practices (GMP) inspection, major deficiency letter, not approvable, or denial.
- *For an original BLA or a BLA efficacy supplement, a resubmission of an original BLA or resubmission of a BLA efficacy supplement, or a BLA manufacturing supplements requiring prior approval*, first action means the issuance of a complete action letter after the complete review of a filed complete application.

16. If FDA determines I should receive a refund, how soon should I expect to receive my refund check?

FDA expects to send you a check for the full amount of your refund within 30 days after we determine you are entitled to a refund.

IV. Sources for Additional Information

17. How can I obtain more information about a particular appeals process?

You can obtain additional information and guidance on FDA's appeals processes by reviewing the guidance documents and SOPPs referenced in this document. If you still have a question, contact —

CBER Ombudsman: (For information about CBER appeals)

CBER Ombudsman (HFM-4)
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Phone: 301-827-0379
Internet site: www.fda.gov/cber/inside/ombudsman.htm

CDRH Ombudsman: (For information about CDRH appeals)

CDRH Ombudsman (HFZ-5)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Phone: 301-827-7991
Internet site: www.fda.gov/cdrh/ombudsman

FDA Ombudsman: (For information about an appeal of FDA's designation of the primary review process for a combination product.)

Office of the Ombudsman (HF-7)
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane
Room 14B03
Rockville, MD 20857

Phone: 301-827-3390
Internet site: www.fda.gov/oc/ombudsman/homepage.htm
E-mail: ombuds@oc.fda.gov

FDA Office of Combination Products: (For information about how OCP can help facilitate the resolution of issues concerning timeliness of reviews of combination products.

Office of Combination Products (HFG-3)
Office of the Commissioner
Food and Drug Administration
Suite 200
15800 Crabbs Branch Way
Rockville, MD 20855

Phone: 301-427-1934
Internet site: www.fda.gov/oc/ombudsman/homepage.htm
E-mail: combination@fda.gov

18. How can I obtain more information about MDUFMA?

For general information about MDUFMA, visit FDA's web sites at —

- www.fda.gov/cdrh/mdufma — Provides the full text of the law, plain-language summaries, answers to frequently-asked questions, *Federal Register* notices, important announcements, guidance documents, and more.
- www.fda.gov/cber/mdufma/mdufma.htm — Similar information, with a focus on biologics devices.

For additional information on MDUFMA user fees and refunds, see —

- *User Fees and Refunds for Premarket Notification Submissions (510(k)s)*, available at — www.fda.gov/cdrh/mdufma/guidance/1511.pdf.
- *User Fees and Refunds for Premarket Approval Applications*, available at — www.fda.gov/cdrh/mdufma/guidance/1224.pdf.