Regulatory Education for Industry (REdI):
GENERIC DRUGS FORUM

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GDUFA User Fee Payments

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GDUFA User Fees Time Line

FY 2016 runs from Oct. 1, 2015 through Sept. 30, 2016

May 1, 2015
June 1, 2015

First week of August 2015

October 1, 2015

- **Facilities fees are due on October 1 of each year**
- **ANDA/PAS filing fee are due at the time of submission**
- **DMF fee is incurred on first reference of that DMF**
- **PET exception**
- **No small business waivers or exceptions**

Facilities Fee

- **The facility fee is incurred:**
  - ✓**for those facilities referenced**
  - ✓**in a pending or approved**
  - ✓**generic drug submission**
  - ✓**as of the fee due date**

Beware of:

- **Cross over period**
- **Correct FEI on coversheets**
- **Correct business operation(s) for each FEI**

Question #38

- **In the second version of the GDUFA Q&A Draft Guidance (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM316671.pdf).**
- **This procedure allows a facility to revoke its letter of authorization for a sponsor to reference that facility.**
- **Notify both my office and the Office of Generic Drugs of the revocation of this authorization.**

Form 356H and its Contents

- **Be sure to use the current 356H form (Exp. 12/31/17) (http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm082348.pdf).**
- **Always include the current POC for the submission and the facilities.**
- **Keep the facilities reference up-to-date.**
- **Provide complete facility information (FEI, address, DUNS, etc).**
- **List all functions performed by each facility.**

Refund Process

Refunds issued for

- ✓Payments made in error (§ 744B(m))
  - ✓Must be requested within 180 days of payment

Note

No refunds are issued for fee-related RTRs issued by the Office of Management

Refund Process, continued

Refunds issued for:

- ✓Refuse to Receive issued by OGD a 75% refund is issued

Internal Process

- **Refunds are normally processed 1-3 months after an RTR**
  - ✓You can request a refund via email right after you receive the RTR letter
  - ✓If you plan to resubmit, we can hold the funds

§ 10.75

- **If all else fails, and you feel the Agency has taken an adverse action in error, there is a provision in the Code of Federal Regulations for you to seek relief.**
- **21 CFR 10.75 outlines a procedure for seeking to have an Agency decision re-evaluated and, potentially, overturned.**
- **The first level of review is with the body that made the initial decision; subsequent reviews are conducted by that person's supervisor, and eventually through the Center Director to the Chief Scientist.**

GDUFA Payments

Top 10 Ways to Ensure That Your GDUFA Payment Goes Wrong…

#10: Forget to account for the wire transfer fee

- **Some financial institutions will charge you a fee to handle a wire transfer.**
- **These fees are typically $10 - $35.**
- **Make sure the amount of your payment includes any wire transfer fees!**

#9: Don’t request a refund timely

- **GDUFA requires that requests for refunds be submitted (a) in writing, and (b) no later than 180 days after the payment was made.**
- **If you feel that you are going to want your money back on a payment, be sure to request a refund before the 180-day clock expires.**
- **Once that clock expires, the Agency is unable to issue a refund.**

#8: Pay someone else

- **Checks need to be made payable to "Food and Drug Administration" or "FDA".**
- **Checks made payable to another entity cannot be processed and will lead to delays in satisfying your user fee obligation.**

#7: Send the payment to someone else

- **Payment instructions provide an address to which payments should be sent.**
- **Sending payments to a different bank or lockbox will result in delays or prevent the Agency from applying your payment in a timely manner.**
- **https://www.federalregister.gov/articles/2014/08/01/2014-18108/generic-drug-user-fee-abbreviated-new-drug-application-prior-approval-supplement-drug-master-file#h-14**

#6: Don't tell us where to apply the funds

- **Completing the cover sheet will provide you with a Payment Identification Number (PIN).**
- **This PIN is essential to allow us to connect your payment to your obligation.**
- **Not providing this PIN will prevent us from applying the funds to the right place – meaning your obligation will not be satisfied.**

#5: Don't communicate with your DMF holder(s)

- **The DMF fee is a one-time only fee, once it's paid it never has to be paid again.**
- **Once the DMF fee has been paid, and OGD has completed an initial completeness assessment, the DMF is listed on a public website.**
- **Communicate with your DMF holder to make sure you don't pay a fee that has already been paid!**

#4: Pay for the wrong fiscal year

- **There is a two-month period each year when you can pay fees for either the current fiscal year or the upcoming fiscal year.**
- **It is important to select the correct fiscal year when completing the cover sheet.**
- **This applies to application, DMF and facility payments.**

#3: Reference the wrong cover sheet

- **When you create a cover sheet, the PIN generated is designed to be unique.**
- **Some people re-use these numbers and wind up paying the same obligation multiple times.**
- **Wrong fiscal year.**
- **PIN for a different facility.**

#2: Use the form 356h incorrectly

- **The form is updated periodically – make sure you use the current one!**
- **Include all the facility FEI numbers.**
- **Include all the DMFs referenced in the application.**
- **Specify the packaging type – not all types incur fees.**

#1: Don't withdraw your facility from submissions you don't support

- **GDUFA imposes fee obligations on certain facilities that are mentioned in pending or approved generic drug submissions.**
- **Before GDUFA, sponsors would include back-up facilities in their applications.**
- **Those facilities now can owe fees even if they're not aware that they're listed in the applications.**

Resources

- **GDUFA Q&A Guidance:**
- **http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM316671.pdf**
- **CDER's Division of User Fee Management & Budget Formulation:**
  - **CDERCollections@fda.hhs.gov**
  - **301-796-7900**

Questions?

Evaluation: surveymonkey.com/s/GDF-D2S7