July 31, 2017

Dear Colleague:

In anticipation of the passage of the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), relevant to FDA's planned approach for administering prescription drug program fees under that legislation for fiscal year (FY) 2018,[1] we are asking you to verify your company's contact information and PDUFA user fee-eligible products by **August 15, 2017**.

For more information regarding reauthorization, please visit https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm446608.htm.

I. Review Your Company's Products

Attachment A – Company Contact Information

Attachment A contains the contact information FDA has for the person designated by your company to receive correspondences, invoices, and inquiries concerning prescription drug user fees. Please review and make corrections on Attachment A or confirm that the information is correct as listed, and return the signed form by email to the PDUFA User Fee staff (CDERCollections@fda.hhs.gov).

Attachment B – Product List

Please review your existing product list, and cross out any products that you believe should not be assessed a fee and include the reason why it should not be assessed a fee (e.g., generic competition for new drug application (NDA) products, revocation or discontinuation of a biological product).

If any product is omitted that should be included on the existing product list, please add the relevant product information on the "Missing PDUFA Eligible Products List" and include the reason why it should be assessed a fee. **Please make your changes directly on the lists provided in Attachment B rather than creating a separate list.**

II. Confirm Your NDA Prescription Drug Products in the Orange Book

A list of user fee-eligible *prescription drug products* for which the Center for Drug Evaluation and Research (CDER) has regulatory responsibility can be found in the Prescription Drug Product List of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book), available at https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

After making any necessary updates to the list of your products in Attachment B, we recommend reviewing your company's current list of drug products in the Orange Book and notifying the Orange Book staff (OrangeBook@fda.hhs.gov) in writing about any changes (e.g., drug products that are no longer marketed)

[1] FY 2018 = October 1, 2017, through September 30, 2018.

U.S. Food & Drug Administration
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Silver Spring, MD 20903
www.fda.gov

to the Prescription Drug Product List **no later than August 31, 2017.** For the Orange Book staff to receive changes in a consistent format, please print your company's list of products from the FDA website and note any changes directly on the printed list. Please send the User Fee staff (CDERCollections@fda.hhs.gov) a courtesy copy of any information sent to the Orange Book staff.

If you notify the Orange Book staff of a drug product's marketing status after August 31, 2017, the product may be included on the invoice for the next FY. You may be eligible for a refund of the assessed user fee provided the Orange Book staff receives the notification to move a product from the Prescription Drug Product List to the Discontinued Product List no later than **September 30, 2017**. To be eligible for a refund, you must submit the refund request in writing to the User Fee staff no later than 180 days after the fee is due.[2]

Failure to move a product to the discontinued section of the Orange Book could result in the assessment of fees, even if the product is not marketed. If you plan to resume marketing your drug product and that product is on the Discontinued Drug Product List, you should notify the Orange Book staff to move the drug product to the Prescription Drug Product List.

III. Confirm Your Biological Products on the CDER and CBER Lists

For a current list of user fee-eligible licensed *therapeutic biological products* for which **CDER** has regulatory responsibility, please see the CDER Billable Biologic Product List at https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM164641.pdf.

For a current list of user fee-eligible licensed *biological products* for which the Center for Biologic Evaluation and Research (**CBER**) has regulatory responsibility, please see the CBER Billable Biologic Product List at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122936.htm.

We recommend reviewing the information on both websites to obtain a complete list of your biological products. If you are no longer marketing a biological product and have delisted it under § 510 of the FD&C Act (21 U.S.C. § 360), but the product is on either of the billable biologics lists, contact the User Fee staff and request in writing that FDA move it to the Discontinued Products List.

Please notify FDA by **August 31, 2017**, if changes need to be made:

- For CDER biological products, email the CDER User Fee staff at CDERCollections@fda.hhs.gov.
- For CBER biological products, email the CBER User Fee staff at CBERPDUFAstaff@fda.hhs.gov. Please include CDERCollections@fda.hhs.gov on correspondences sent to the CBER User Fee staff.

If you notify the User Fee staff to discontinue marketing a biological product after August 31, 2017, the product may be included on the invoice for the next FY. You may be eligible for a refund of the assessed user fee provided the User Fee staff receives the notification to move a product to the Discontinued Product

[2] Section 736(i) of the FD&C Act (21 U.S.C. § 379h(i)).

List no later than **September 30, 2017**. To be eligible for a refund, you must submit the refund request in writing to the User Fee staff no later than 180 days after the fee is due.[3]

Failure to move a product to the Discontinued Product List of CDER or CBER Billable Biologic Product List could result in the assessment of fees, even if the product is not marketed. If you plan to resume marketing your biological product and it is on the Discontinued Product List, you should notify the User Fee staff so the product can be moved to the appropriate billable biologic product list.

IV. How to Provide the Requested Information

Please return Attachments A and B (including the updated product list) by **August 15, 2017**, by email to the PDUFA User Fee staff at CDERCollections@fda.hhs.gov.

V. PDUFA Email Listserv

We have created an email listserv to disseminate important news and information regarding PDUFA. You may subscribe to the "Prescription Drug User Fee Act (PDUFA)" email listserv at https://www.fda.gov/AboutFDA/ContactFDA/StayInformed/GetEmailUpdates/default.htm#userfeeprograms.

If you have questions, please email (CDERCollections@fda.hhs.gov) or call (301-796-7900) and ask to speak to the PDUFA User Fee staff.

We look forward to receiving your responses by **August 15, 2017.**

Sincerely,

Lisa A. Berry -S

Digitally signed by Lisa A. Berry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Lisa A. Berry -S, 0.9.2342.19200300.100.1.1=2000386972
Date: 2017.07.26 18:14:58 -04'00'

Lisa Berry, Acting Director
Division of User Fee Management & Budget Formulation
Office of Management
Center for Drug Evaluation and Research
US Food and Drug Administration

Attachments:
Attachment A – Company Contact Information
Attachment B – List of User Fee Eligible Products

[3] Section 736(i) of the FD&C Act (21 U.S.C. § 379h(i)).