
Assessing User Fees Under the Generic Drug User Fee Amendments of 2017

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Office of Management, Division of User Fee Management and Budget Formulation, Phone: 301-786-7900.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**October 2017
User Fees**

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**U.S. Department of Health and Human Services
Food and Drug Administration
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1 **Assessing User Fees Under the Generic Drug User Fee**
2 **Amendments of 2017**
3 **Guidance for Industry¹**
4
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6
7 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
8 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
9 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
10 applicable statutes and regulations. To discuss an alternative approach, contact the FDA office
11 responsible for this guidance as listed on the title page.
12

13
14 **I. INTRODUCTION**
15

16 This guidance provides stakeholders information regarding FDA’s implementation of the
17 Generic Drug User Fee Amendments of 2017 (GDUFA II) under Title III of the FDA
18 Reauthorization Act of 2017. Because GDUFA II created changes to the user fee program, this
19 guidance serves to provide an explanation about the new fee structure and types of fees for
20 which entities are responsible.
21

22 This guidance describes the types of user fees authorized by GDUFA II, the process for
23 submitting payments to FDA, the consequences for failing to pay generic drug user fees, and the
24 process for requesting a reconsideration of a user fee assessment. This guidance also describes
25 how FDA determines affiliation for purposes of assessing generic drug user fees. FDA will
26 issue separate guidance documents regarding GDUFA II non-user fee requirements and
27 processes. This guidance does not address how FDA determines and adjusts fees each fiscal
28 year; nor does it address FDA’s implementation of other user fee programs (e.g. Prescription
29 Drug User Fee Amendments, Biosimilar Biological User Fee Amendments).² Throughout this
30 guidance, references to *user fees* or the *user-fee program* are to generic drug user fees collected
31 under section 744B of the Federal Food Drug and Cosmetic Act (FD&C Act).
32

33 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
34 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
35 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
36 the word *should* in Agency guidances means that something is suggested or recommended, but
37 not required.
38

¹ This guidance has been prepared by the Division of User Fee Management and Budget Formulation, Office of Management, in the Center for Drug Evaluation and Research at the Food and Drug Administration.

² FDA will publish in the *Federal Register* the fee revenue and fee amounts for each fiscal year not later than 60 days before the start of each fiscal year. Section 744B(d)(1) of the FD&C Act.

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39 Changes to statutory provisions that are described in this guidance are effective with respect to
40 fees assessed beginning on the first day of fiscal year (FY) 2018.

41

42 **II. BACKGROUND**

43

44 The Generic Drug User Fee Amendments of 2012 (GDUFA I) added sections 744A and 744B to
45 the FD&C Act, authorizing FDA to collect user fees for a 5-year period from persons that submit
46 certain abbreviated new drug applications (ANDAs) for review, or that are referenced in certain
47 ANDAs. Fees authorized by this legislation help fund the process for the review of generic drug
48 applications and have played an important role in expediting the drug review and approval
49 process. GDUFA was reauthorized for a five-year period in 2017 (GDUFA II) under the FDA
50 Reauthorization Act of 2017, enacted on August 18, 2017.

51

52 GDUFA II extends FDA's authority to collect user fees for FY³ 2018 to FY 2022 and revised the
53 fees that the Agency collects and how it collects some fees. Discussions about the further
54 reauthorization of GDUFA are expected to begin before or during FY 2022, the final fiscal year
55 of GDUFA II.

56

57

58 **III. DEFINITIONS**

59

60 For purposes of this guidance:

61

62 • The term ***abbreviated new drug application*** means an application submitted under section
63 505 of the FD&C Act (21 U.S.C. § 355(j)), under former section 507 of the Act (now
64 repealed), or pursuant to regulations in effect prior to the implementation of the Drug Price
65 Competition and Patent Term Restoration Act of 1984. The term does not include an
66 application for a positron emission tomography drug and does not include an application
67 submitted by a State or Federal Government entity for a drug that is not distributed
68 commercially.⁴

69

70 • The term ***active pharmaceutical ingredient*** means a substance, or a mixture when the
71 substance is unstable or cannot be transported on its own, intended (A) to be used as a
72 component of a drug; and (B) to furnish pharmacological activity or other direct effect in
73 the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure
74 or any function of the human body; or a substance intended for final crystallization,
75 purification, or salt formation, or any combination of those activities, to become a
76 substance or mixture as described above.⁵

77

³ FDA's fiscal year begins on October 1 and ends on September 30.

⁴ See Section 744A(1) of the FD&C Act.

⁵ See Section 744A(2) of the FD&C Act.

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- 78 • The term ***affiliate*** means a business entity that has a relationship with a second business
79 entity if, directly or indirectly (A) one business entity controls, or has the power to control,
80 the other business entity; or (B) a third party controls, or has power to control, both of the
81 business entities.⁶
82
- 83 • The term ***facility*** means a business or other entity under one management, either direct or
84 indirect, and at one geographic location or address engaged in manufacturing or processing
85 an active pharmaceutical ingredient or a finished dosage form. The term facility does not
86 include a business or other entity whose only manufacturing or processing activities are
87 one or more of the following: repackaging, relabeling, or testing.⁷
88
- 89 • The term ***finished dosage form*** means (A) a drug product in the form in which it will be
90 administered to a patient, such as a tablet, capsule, solution, or topical application; (B) a
91 drug product in a form in which reconstitution is necessary prior to administration to a
92 patient, such as oral suspensions or lyophilized powders; or (C) any combination of an
93 active pharmaceutical ingredient with another component of a drug product for purposes
94 of production of a drug product described in subparagraph (A) or (B).⁸
95
- 96 • The term ***generic drug submission*** means an abbreviated new drug application, an
97 amendment to an abbreviated new drug application, or a prior approval supplement to an
98 abbreviated new drug application.⁹
99
- 100 • The term ***positron emission tomography drug*** means a drug that exhibits spontaneous
101 disintegration of unstable nuclei by the emission of positrons and is used for the purpose
102 of providing dual photon positron emission tomographic diagnostic images, and includes
103 any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target
104 material, electronic synthesizer, or other apparatus or computer program to be used in the
105 preparation of such a drug.¹⁰
106
- 107 • The term ***prior approval supplement*** means a request to the Secretary to approve a change
108 in the drug substance, drug product, production process, quality controls, equipment, or
109 facilities covered by an approved abbreviated new drug application when that change has
110 a substantial potential to have an adverse effect on the identity, strength, quality, purity, or
111 potency of the drug product as these factors may relate to the safety or effectiveness of the
112 drug product.¹¹

⁶ See Section 744A(4) of the FD&C Act.

⁷ See Section 744A(6) of the FD&C Act. The FDA Establishment Identifier (FEI) is used to identify unique facilities.

⁸ See Section 744A(7) of the FD&C Act.

⁹ See Section 744A(8) of the FD&C Act.

¹⁰ See Section 744A(10) of the FD&C Act; See Section 201(ii) of the FD&C Act.

¹¹ See Section 744A(11) of the FD&C Act.

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- The term ***Type II active pharmaceutical ingredient drug master file*** means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.¹²
- The term ***contract manufacturing organization facility*** means a manufacturing facility of a finished dosage form of a drug approved pursuant to an ANDA which is not identified in an ANDA held by the owner of that facility or its affiliates.¹³

IV. CHANGES TO THE STRUCTURE OF THE GDUFA USER FEE PROGRAM

GDUFA II authorizes the collection of five types of fees: (1) backlog fees; (2) drug master file (DMF) fees; (3) ANDA filing fees; (4) active pharmaceutical ingredient (API) and finished dosage form (FDF) facility fees; and (5) generic drug applicant program fees (GDUFA Program Fees). The statute directs FDA to set annual fee amounts for each fiscal year so that DMF fees will account for 5 percent, ANDA fees 33 percent, API facility fees 7 percent, FDF facility fees 20 percent, and GDUFA Program Fees 35 percent of the total revenue amount determined for a fiscal year.¹⁴ Under GDUFA II, applications submitted by State and/or Federal government entities for drugs that are not distributed commercially also do not incur fees.

Previously, section 744B of the FD&C Act authorized FDA to collect (1) backlog fees; (2) DMF fees; (3) ANDA and prior approval supplement (PAS) fees; and (4) API and FDF facility fees. GDUFA II establishes a new fee structure that eliminates PAS fees and adds GDUFA Program Fees.

Additionally, facilities that manufacture both APIs and FDFs will only incur FDF fees instead of owing both API and FDF facility fees. A facility no longer incurs a fee if it is only referenced in pending generic drug submissions because the facility fee obligation now applies only to facilities referenced in approved generic drug submissions. Facilities that qualify as contract manufacturing organizations (CMOs) pay one-third the amount of the facility fee incurred by FDF facilities that do not qualify as CMOs.¹⁵

¹² See Section 744A(13) of the FD&C Act.

¹³ See Section 744A(5) of the FD&C Act; See Section IV (Changes to the Structure of the GDUFA User Fee Program) and Section VII (Facility Fees) for more information.

¹⁴ See Section 744B(b) of the FD&C Act. While in almost all cases applicants that owed backlog fees have now paid those fees, this obligation remains part of the statute.

¹⁵ See Section 744B(b)(2)(C) of the FD&C Act.

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148 The Agency will continue to establish generic drug user fees for each fiscal year based on
149 revenue amounts set forth in the statute, and will publish the fees and fee revenue amounts for a
150 fiscal year in the Federal Register not later than 60 days before the start of that year.¹⁶

151

152

V. BACKLOG FEES

154

155 Under GDUFA II, each person that owns an ANDA that was pending on October 1, 2012, and
156 that has not received a tentative approval prior to that date, owes a backlog fee for each such
157 application.¹⁷

158

159 The backlog fee was due no later than November 26, 2012. The final backlog fee is \$17,434.
160 See *Federal Register* notice: “Generic Drug User Fee – Backlog Fee Rate for Fiscal Year 2013”
161 for additional details (available at <https://www.gpo.gov/fdsys/pkg/FR-2012-10-25/pdf/2012-26257.pdf>).
162

163

164 An original ANDA was considered to be pending and subject to the backlog fee, if, as of
165 September 28, 2012, FDA had not tentatively approved, approved, or refused to receive (RTR)
166 the application.¹⁸ See *Federal Register*: “Notice of Opportunity to Withdraw Abbreviated New
167 Drug Applications to Avoid Backlog Fee Obligations” for additional details (available at
168 <https://www.gpo.gov/fdsys/pkg/FR-2012-08-27/html/2012-20947.htm>).
169

170

171

VI. DRUG MASTER FILE FEES

172

173 Each person that owns a Type II active pharmaceutical ingredient DMF that is referenced on or
174 after October 1, 2012, in a generic drug submission by any initial letter of authorization is
175 assessed a one-time DMF fee under GDUFA II.¹⁹

176

177 The DMF fee is due on whichever of the following dates occurs earlier:

178

- 179 • The date on which the first generic drug submission is submitted that references the
180 associated Type II API DMF by an initial letter of authorization; or
- 181 • The date the DMF holder requests the initial completeness assessment.²⁰

182

¹⁶ Section 744B(a) of the FD&C Act.

¹⁷ See Section 744B(a)(1)(A) of the FD&C Act; GDUFA II contains a sunset provision of October 1, 2022, for backlog fees; See Section 744B(a)(1)(E) of the FD&C Act.

¹⁸ Receipt of an ANDA means that FDA has made a threshold determination that the ANDA is sufficiently complete to permit a substantive review. 21 CFR § 314.101(b)(1).

¹⁹ See Section 744B(a)(2)(A) of the FD&C Act.

²⁰ See Section 744B(a)(2)(E)(i) of the FD&C Act.

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183 For a DMF referenced in an ANDA prior to GDUFA I implementation, the one-time DMF fee
184 must be paid if the DMF is newly referenced in a generic drug submission on or after October 1,
185 2012.

186
187 Type II API DMF holders do not need to wait for a new ANDA applicant to request a letter of
188 authorization before the DMF is assessed to be available for reference. DMF holders can pay
189 the fee before a letter of authorization is requested. The DMF will then undergo an initial
190 completeness assessment, using factors articulated in the final guidance *Completeness*
191 *Assessments for Type II API DMFs Under GDUFA* (available at
192 [https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf)
193 [UCM321884.pdf](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf)). If the DMF passes the initial completeness assessment, FDA will include the
194 DMF on the Type II Drug Master Files – Available for Reference List (available at
195 <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM332875.xls>).

196
197

VII. ABBREVIATED NEW DRUG APPLICATION FILING FEES

199

200 GDUFA II levies a user fee on certain human generic drug applications. A fee is assessed for
201 each ANDA submitted to FDA after October 1, 2012. A prior approval supplement filing fee,
202 which was required under GDUFA I, is no longer required under GDUFA II.²¹

203

204 ANDA fees are due on the date of submission of the application.²²

205

A. Refund for Refusal to Receive and Withdrawals and Inappropriate Receipts

206
207

208 If FDA refuses to receive an ANDA for reasons not related to failure to pay fees, then 75 percent
209 of the filing fee paid will automatically be refunded to the applicant. Under GDUFA II, a 75
210 percent refund of the application filing fee paid will also be remitted for an application that has
211 been withdrawn prior to being received within the meaning of section 355(j)(5)(A) of the FD&C
212 Act.²³

213

214 If FDA initially receives an ANDA and subsequently determines that exclusivity should have
215 prevented that receipt so that the ANDA is no longer considered received, FDA will refund
216 100% of the fee paid for that ANDA.²⁴

217

²¹ Unpaid fees for supplements submitted under GDUFA I will not automatically be considered met once GDUFA II takes effect in FY 2018. These supplements will continue to be considered as refused to receive by the Agency. The ANDA applicant may submit a new supplement in FY 2018 under GDUFA II, which will not incur a supplement fee.

²² See Section 744B(a)(3)(C)(i) of the FD&C Act.

²³ See Section 744B(a)(3)(D)(i) of the FD&C Act.

²⁴ See Section 744B(a)(3)(D)(ii) of the FD&C Act.

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218 Although certain GDUFA refunds are automatic, FDA encourages applicants to submit refund
219 requests as soon as possible to expedite the refund process. To request a refund, applicants
220 should fill out Form FDA 3913 and email the form to CDERCollections@fda.hhs.gov. Form
221 FDA 3913 is attached as Appendix 1, and available on the internet at
222 <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

223
224 Include the Tax ID number (required for all domestic companies) or DUNS number (required for
225 all foreign companies), and the address where the refund should be sent. This information is
226 required, and FDA cannot process a refund without it. If an applicant does not submit a refund
227 request, FDA will initiate a refund during its periodic review of outstanding refunds.

228
229 If an application that FDA previously refused to receive is resubmitted, the applicant will be
230 required to pay the full fee at the time of resubmission. Similarly, an applicant who withdraws
231 an application before it is received and then submits a new ANDA for that product must pay the
232 full fee upon submission. If the applicant notifies FDA that it plans to resubmit the application
233 in the near future, the Agency may hold the refund and initiate a transfer of the funds to the
234 resubmission upon the request of the applicant. To request a transfer, applicants should fill out
235 Form FDA 3914 and email the form to CDERCollections@fda.hhs.gov. Form FDA 3914 is
236 attached as Appendix 2, and available on the internet at
237 <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492195.pdf>.

B. Resubmissions

238
239
240
241 A resubmission of an ANDA attempts to remedy deficiencies (major, minor, Electronic Common
242 Technical Document) indicated in a RTR letter. A full ANDA filing fee is due upon
243 resubmission of the ANDA that FDA refused to receive. Dispute of a RTR decision without
244 attempting to remedy the deficiencies is not considered a resubmission and is therefore not
245 subject to a new ANDA filing fee.

C. Exemptions to the Application Filing Fee

246
247
248
249 An applicant will not incur an ANDA filing fee under the following circumstances:

- 250
- 251 • The application is for a positron emission tomography (PET) drug;
 - 252 • The application is submitted by a State or Federal Government entity for a drug that is not
253 distributed commercially; or
 - 254 • The submitted application is a serial submission (see subsection E. below).
- 255

256 Approved applications of the types described in this subsection will also not be considered in
257 determination of GDUFA Program Fees (see section IX below).

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259 **D. Fee for API Information Not Included by Reference to DMF - (a)(3)(F) Fee**

260

261 An applicant is required to pay an API information fee for a generic drug submission:

262

- 263 • That contains information concerning the manufacture of an API at a facility by means
- 264 other than reference by a letter of authorization to a Type II active pharmaceutical DMF;
- 265 and
- 266 • For which a fee in the amount equal to the DMF fee has not been previously paid.

267

268 Similar to the DMF fee, this fee is paid only once.²⁵

269

270 GDUFA II specifies that an additional API information fee must be paid for each manufacture of
271 an API by one facility described in an application, when such a fee has not already been paid for
272 the manufacture of that API by that facility. Therefore, the total amount of the API information
273 fees for a particular application is a function of the number of APIs referenced in the application
274 and the number of facilities in which those APIs are manufactured. The API information fee
275 must be paid for each manufacture of an API by a particular API facility, provided a DMF or API
276 information fee has not already been paid for the manufacture of the same API by the same facility.

277

278 Because the calculation is potentially confusing, please see the following two examples:

279

280 **Example One:**

281

282 An applicant (XYZ Corp.) submits an ANDA that, rather than referencing a DMF, describes the
283 manufacture of three APIs at one or more facilities. No previous API information or DMF fee
284 has been paid for the manufacturing of the APIs by these facilities.

285

Product	API	Facility that has not paid API fee
Drug X	Alpha	1, 2, 3
	Beta	1, 2
	Gamma	1

286

287 In this example, XYZ Corp. owes the following API information fee:

288

289 Fee = (APIs (Alpha + Beta + Gamma) + extra facilities (Alpha 2 + Alpha 3 + Beta 2)) x DMF
290 Fee Amount

291

292 = (3 APIs + 3 extra facilities) x DMF Fee Amount

293

294 = 6 x DMF Fee Amount

²⁵ See Section 744B(a)(3)(F) of the FD&C Act.

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295

296 **Example Two:**

297

298 XYZ Corp. then submits a new application for a second product with the following information
299 about API manufacture other than by reference to a DMF:

300

Product	API	Facility
Drug Y	Alpha	1, 2, 3
	Beta	1, 2
	Gamma	1, 2
	Delta	1

301

302 The one-time fee has already been paid for the description of the manufacture of API Alpha at
303 Facility 1, 2, and 3; API Beta at Facility 1 and 2; and API Gamma at Facility 1, so no additional
304 fee is due with respect to these facilities.

305

306 The applicant owes an API information fee for the following:

307

308 Fee = (additional API Delta + manufacture of API Gamma at Facility 2 x DMF Fee Amount

309

310 = (1 API + 1 extra facility) x DMF Fee Amount

311

312 = 2 x DMF Fee Amount

313

314 The fees, referenced in the above calculations, for each API manufacturing facility that
315 manufactures a particular API included in an application is meant to replicate the applicable DMF
316 fee if the information had been submitted in a DMF. Annual API facility fees are discussed
317 below and are required for each facility that is identified in an ANDA or a DMF.

318

319 **E. Serially Submitted ANDAs**

320

321 In some circumstances, ANDA applicants choose to serially submit complete ANDAs containing
322 “paragraph IV certifications” in anticipation of a patent being listed for a reference listed drug.²⁶
323 Note that under 21 CFR § 314.94, serial submissions are prohibited: “for a paragraph IV
324 certification, the certification must not be submitted earlier than the first working day after the
325 day the patent is published” in FDA’s “Approved Drug Products With Therapeutic Equivalence
326 Evaluations,” commonly known as the Orange Book. The regulation reflects FDA’s judgment
327 that permitting serial submissions of amendments and multiple notices of paragraph IV

²⁶ For a description of ANDA patent certifications see draft guidance for industry *180-day Exclusivity: Questions and Answers* (Jan 2017) available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536725.pdf>.

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328 certifications is overly burdensome to FDA and NDA holders.²⁷ Applications submitted prior to
329 the time specified in the cited regulation are not considered to be in the possession of the
330 Agency. However, applicants who nonetheless choose to serially submit complete ANDAs in
331 anticipation of a new patent being listed in the Orange Book should remit their application filing
332 fee on the first working day after the day the relevant patent is listed in the Orange Book or, if the
333 application is not submitted on that date, on the date the application is submitted.

334

F. Withdrawn ANDAs

336

337 Once a fee is incurred, it must be paid notwithstanding what happens to the application.
338 Accordingly, an ANDA that is withdrawn still owes the fee. However, if an application is
339 withdrawn before being received, the applicant is eligible for a 75% refund.

340

341

VIII. FACILITY FEES

343

344 Under GDUFA II, the owner of a facility incurs a fee when both of the following conditions are
345 met on the facility fee due date:

346

- 347 • The facility is referenced in an *approved* generic drug submission; and
- 348 • The facility is engaged in manufacturing or processing an API or FDF.²⁸

349

350 A facility does not incur a fee for being referenced only in *pending* generic drug submissions in
351 GDUFA II.

352

353 Note that an entity meeting the two criteria above will incur a facility fee liability regardless of
354 whether it is manufacturing or producing generic *or* non-generic human drugs. For example, if a
355 facility is referenced in an approved ANDA and is manufacturing only brand-name drugs, it will
356 be assessed a facility fee under GDUFA II.

357

358 Facility fees are due on the later of the first business day on or after October 1 of each fiscal year,
359 or the first business day after the enactment of an appropriations Act providing for the
360 collection and obligation of fees for such year.²⁹

361

362 If a facility is first identified in an approved generic drug submission after the due date for
363 payment of the facility fee for a fiscal year, the facility is not required to pay the fee for that
364 fiscal year.

365

²⁷ See 81 FR 69580, 69610.

²⁸ See Section 744B(a)(4)(A) of the FD&C Act; See Section 744A(5) of the FD&C Act.

²⁹ See Section 744B(a)(4)(D) of the FD&C Act.

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366 **A. API and FDF Facility Fees**

367

368 Each person that owns a facility will incur an API facility fee when the facility is identified in:

369

- 370 • At least one generic drug submission in which the facility is approved to produce one or
- 371 more APIs, or
- 372 • A Type II API DMF referenced in an approved generic drug submission.³⁰

373

374 Each person that owns a facility will incur an FDF facility fee when the facility is identified in at

375 least one generic drug submission that is approved to produce one or more FDFs.³¹

376

377 **B. Exceptions to Facility Fees**

378

379 The following entities will not incur facility fees under GDUFA II:

380

- 381 • Facilities that solely produce PET drugs.
- 382 • Facilities that are only listed in applications submitted by State and/or Federal
- 383 government entities for drugs that are not distributed commercially.
- 384 • Facilities whose only manufacturing or processing activities are one or more of the
- 385 following: repackaging, relabeling, or testing.

386

387 **C. Dual Operation Facilities Only Incur FDF Facility Fees**

388

389 If a facility is identified in one or more approved generic drug submissions to produce both APIs

390 and FDFs, the facility will only incur an FDF fee.³² This differs from the treatment under

391 GDUFA I, which required that such facilities pay both API and FDF fees.

392

393 **D. Contract Manufacturing Organizations**

394

395 CMOs are independent firms with no ownership stake (either directly or through affiliates) in the

396 ANDAs for the drug products they manufacture. An FDF manufacturer facility that is not

397 identified in an approved ANDA held by the owner of that facility or its affiliates is considered a

398 CMO for GDUFA user fee purposes.³³

399

400 For example, if the FDF facility is referenced in an ANDA held by its owner, that FDF facility

401 would not be a CMO. However, even if the owner of the FDF facility holds an ANDA, so long

402 as the facility is not referenced in its owner's or its owner's affiliates' ANDAs, then it qualifies

403 as a CMO and pays one-third the amount of the FDF facility fee if referenced in another

³⁰ See Section 744B(a)(4)(A)(ii) of the FD&C Act.

³¹ See Section 744B(a)(4)(A)(iii) of the FD&C Act.

³² *Id.*

³³ See Section 744A(5) of the FD&C Act.

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404 ANDA.³⁴ Similarly, if an FDF facility owner is affiliated with Company X, and Company X
405 references that FDF facility in its ANDA, the FDF facility is not a CMO.

406
407 A facility's qualification as a CMO depends only on the FDF manufacturing activities of that
408 facility. A facility that is referenced in one or more ANDAs as both an API and FDF
409 manufacturer may qualify as a CMO even if it is referenced as an API manufacturer in its own or
410 its affiliates' ANDA. As long as a dual facility is not referenced as an FDF manufacturer in its
411 own or its affiliates' ANDAs, it may qualify as a CMO.

412

E. Foreign-Facility Fee Differential

413

414
415 GDUFA II specifies that the amount of the fee for a facility located outside the United States and
416 its territories and possessions is \$15,000 higher than the amount of the fee for a domestic facility.
417 For example, a foreign facility will pay one-third the FDF facility fee plus \$15,000.³⁵ The
418 \$15,000 differential applies to all facilities that incur a fee under GDUFA II, including those
419 facilities defined as CMOs. The differential amount is designed to reflect the higher costs of
420 foreign inspections funded, in part, through GDUFA II.

421

F. Withdrawal of Facility From Reference

422

423
424 If an ANDA sponsor determines that a manufacturing facility no longer manufactures its API or
425 FDF and the ANDA sponsor no longer seeks to retain the facility as an approved manufacturer of
426 the API or FDF, the ANDA sponsor should submit an appropriate notification to remove the
427 manufacturing facility from the ANDA. The supplement should provide a justification if the site
428 being removed is not considered redundant (i.e., the particular facility's manufacturing role is not
429 replaced by another appropriate site to continue the approved function). If approval of another
430 facility is desired, the notification to remove the prior facility may be included in the supplement
431 to add the new facility to the ANDA. If a facility identified in an ANDA wishes to be removed
432 from that ANDA, the Agency encourages the owner of the facility to contact the ANDA sponsor
433 and/or DMF holder and work together to effect the facility's removal from the application.

434

435 In the rare situation when the ANDA sponsor or DMF holder does not file a notification to
436 remove an approved manufacturing facility for its API or FDF, a facility may remove itself from
437 reference in all ANDAs to prevent incurring future user fees through the process described in the
438 following paragraphs.

439

440 An ANDA sponsor can identify a facility that it does not own in its application only if the owner
441 of that facility has provided the ANDA sponsor permission to refer to the facility. If the owner
442 of the facility submits a notification to FDA to withdraw that permission—and thus no longer be
443 approved for use by the ANDA applicant—FDA will consider the facility to be no longer
444 identified in the application as of the date FDA receives notice of the withdrawal via the process

³⁴ See Section 744B(b)(2)(C) of the FD&C Act.

³⁵ *Id.*

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445 described below. The facility will no longer be approved for manufacture of the FDF, or the
446 API, for that application.

447
448 Since a facility continues to incur facility fees until FDA is notified of the facility's withdrawal,
449 the Agency encourages the owner of the facility identified in an ANDA to take the following
450 steps prior to the fiscal year fee due date:

- 451
- 452 • Notify the ANDA sponsor and/or DMF holder in writing that it is withdrawing its
453 permission to reference the facility in its ANDA and/or DMF.
 - 454
 - 455 • Send a copy of this letter to the standard application submission methods for ANDAs and
456 DMFs via FDA electronic gateway or by mail to the ANDA archival file at the following
457 address:

458
459 Office of Generic Drugs (HFD-600)
460 Center for Drug Evaluation and Research
461 Food and Drug Administration
462 Document Control Room
463 Metro Park North VII
464 7620 Standish Pl.
465 Rockville, MD 20855

- 466
- 467 • If the facility owner is also a DMF holder, update the DMF with this change. See
468 FDA's DMF website for more information
469 (<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm>).
470
- 471
- 472 • In addition, email a copy of the withdrawal letter to the Division of User Fee
473 Management and Budget Formulation at CDERCollections@fda.hhs.gov.

474
475 An entity will incur facility fees if it manufactures any human drugs and is referenced in an
476 approved generic drug submission on the facility fee due date, regardless of whether it
477 manufactures only non-generic APIs or FDFs. Similarly, a facility owner will have to pay a
478 facility fee if the facility is referenced in an approved generic drug submission, even if it is only
479 manufacturing drugs for the non-US market. For example, a facility that is only manufacturing
480 one non-generic drug for a non-US market and is referenced in an approved ANDA as an API
481 manufacturer on the facility fee due date will incur an API facility fee.

482
483 Self-identification does not, in and of itself, trigger a liability to pay GDUFA facility fees.
484 Many—but not all—facilities that self-identify are required to pay an annual facility user
485 fee. Those that do incur the fee include facilities manufacturing API of human generic drugs
486 and/or FDF human generic drugs. Other sites and organizations must self-identify but are not
487 required to pay the annual facility user fee. These include facilities that solely manufacture PET

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488 drugs, or sites and organizations that only perform testing, repackaging, or relabeling
489 operations. While repackagers are not required to pay user fees, packagers are, in most cases,
490 FDF or CMO FDF manufacturers and subject to facility fees. Removal of a facility from self-
491 identification will not prevent the facility from incurring facility fees.

492
493 For more information on self-identification, please visit
494 <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>, and see the final
495 guidance *Self-Identification of Generic Drug Facilities, Sites, and Organizations*
496 (<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm316672.pdf>).
497

498
499 If a facility is identified in an approved generic drug submission on the due date, and that
500 reference to the facility or the drug submission is later withdrawn, the fee will not be refunded.
501 Accordingly, withdrawal of all reference to facilities in generic drug submissions after the due
502 date will not absolve the facility owner from the requirement to pay previously incurred facility
503 fees.

G. Packagers and Repackagers

504
505
506
507 Packagers are considered to be manufacturers, regardless of whether that packaging is done
508 pursuant to a contract or by the applicant itself. Such facilities are required to pay annual FDF
509 facility fees. A packaging facility may incur only one-third of the FDF facility fee if it qualifies
510 as a CMO (see definitions section above).

511
512 A facility is considered a packager for the purposes of GDUFA II if it receives product prior to
513 the point in the manufacturing process in which the drug is first packaged in a container/closure
514 system specified in the “How Supplied” section of an approved ANDA and packages that
515 product into such a container/closure system for the first time. Every ANDA specifies the forms
516 or configuration in which the approved drug product may be packaged and distributed in the
517 “How Supplied” section. For example, if a facility receives bulk drugs and packages them into
518 the containers in which they are marketed, it is a packager.

519
520 A facility is also considered to be a manufacturer if it receives product in a container/closure
521 specified in the “How Supplied” section of an approved ANDA and applies the FDA-approved
522 prescription package labeling to that product for the first time.

523
524 Repackagers are not required to pay facility fees under GDUFA II. Repackagers include
525 facilities that remove a drug from a primary container/closure system and subdivide the contents
526 into a different primary container/closure system. For example, a facility that takes tablets out of
527 a plastic bottle and packages the tablets into blister packaging is considered a repackager.³⁶

³⁶ See guidance for industry *SPL Industry Technical Specification Information: Electronic Self-Identification of Generic Drug Facilities or Sites* (2017) at 7, available at <https://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM329269.pdf>.

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H. API and Excipient Mixtures

Generally, manufacturers of API mixtures are required to pay the annual FDF facility fee. However, GDUFA II provides one exception, for fee-paying purposes only, to the definition of in-process mixtures as FDF. GDUFA II defines an API and excipient mixture as an API when it is produced because the API is unstable and cannot be transported on its own. Examples include an API mixed with an antioxidant for chemical stability when the API is prone to oxidative degradation or an API excipient mixture for physical stability to maintain its amorphous form.

I. Atypical APIs

Facilities that process raw materials used to manufacture human generic drugs are generally required to pay annual facility fees if they supply a product that qualifies as an API as defined in GDUFA II. For example, if a facility manufactures an ingredient which is used as a component of a drug and furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, and the ingredient is referenced in an approved ANDA, that facility may incur a facility fee.

J. Facilities That Cease Manufacturing

A facility incurs annual facility fees as long as it is so identified, even if the facility has not started commercial-scale production of the API or FDF covered by that submission, or if the facility has stopped, temporarily or permanently, the production of that API or FDF. See above for a description of how a facility can ensure that it is no longer identified in an ANDA.

The facility will cease to incur additional fees if it is no longer identified in any generic drug submission or has stopped manufacturing *all* APIs and FDFs (including both generic and non-generic APIs and FDFs) by the date that the fee is due. In the latter case, the entity no longer qualifies as a facility under GDUFA II – see the definition of facility in Section III above. Any outstanding fee obligations will, however, remain due.

A facility is encouraged to contact its ANDA holder to withdraw its permission to be referenced in an ANDA or follow the steps outlined in the “Withdrawal of Facility from Reference” section to remove itself from all ANDA references. If a facility goes out of business, it should contact FDA to notify the Agency of its status.

K. Fees for Multiple Locations of the Same Company

If a company’s two locations manufacture a U.S. generic product and they are in different geographic locations, each has to pay an annual facility fee. However, separate buildings within close proximity are considered to be at one geographic location or address if:

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- 571 • The activities in them are closely related to the same business enterprise;
572 • They are under the supervision of the same local management; and
573 • They are capable of being inspected by FDA during a single inspection.³⁷
574

575 These are the same criteria used by the FDA’s Office of Regulatory Affairs to evaluate whether
576 separate FDA Facility Establishment Identifiers (FEIs) are necessary for multiple facilities (see
577 final guidance *Self-Identification of Generic Drug Facilities, Sites, and Organizations*, available
578 at
579 [https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm](https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm316672.pdf)
580 [316672.pdf](https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm316672.pdf)).

581
582 If a firm believes that multiple FEIs have been assigned in error or that its separate facilities
583 qualify for a single FEI, the firm may request consolidation of the FEIs. Once a facility fee is
584 incurred, the fee remains outstanding regardless of whether FDA later agrees to consolidation
585 of FEI numbers. Domestic firms should submit the request to the appropriate FDA District
586 office. Contact information is available at
587 <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123522.pdf>. Foreign firms should
588 contact FDAGDUFAFEIRequest@fda.hhs.gov.
589

IX. GENERIC DRUG APPLICANT PROGRAM FEE

592
593 Under GDUFA II, a GDUFA Program Fee will be assessed annually based on the number of
594 approved applications that an entity and its affiliates own. Affiliated companies will be grouped
595 together and counted as a single entity for purposes of assessing the GDUFA Program Fee.³⁸ An
596 ANDA sponsor and its affiliates cannot choose to pay multiple smaller fees to avoid paying the
597 fee associated with larger tiers.
598

599 GDUFA Program Fees are due on the later of the first business day on or after October 1 of each
600 fiscal year, or the first business day after the enactment of an appropriations Act providing for
601 the collection and obligation of fees for such year.³⁹
602

A. GDUFA Program Fee Structure

603
604
605 The GDUFA Program Fee will be allocated among three tiers of application holders:
606

- 607 • Small (companies with 5 or fewer approved ANDAs).
608 • Medium (companies with between 6 and 19 approved ANDAs).

³⁷ See Section 744A(5) of the FD&C Act. The statute further states that if a business or other entity would meet the definition of a facility but for being under multiple management, the business or entity is deemed to constitute multiple facilities, one per management entity.

³⁸ See Federal Register Notice, 82 FR 2381.

³⁹ See Section 744B(a)(5) of the FD&C Act.

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- 609 • Large (companies with 20 or more approved ANDAs).
610

611 If a person and its affiliates own at least one but not more than five ANDAs on the GDUFA
612 Program Fee due date, the person and its affiliates shall owe a small size operation GDUFA
613 Program Fee equal to one-tenth of the large size operation GDUFA Program Fee.
614

615 If a person and its affiliates own at least six but not more than 19 ANDAs on the GDUFA
616 Program Fee due date, the person and its affiliates shall owe a medium size operation GDUFA
617 Program Fee equal to two-fifths of the large size operation GDUFA Program Fee.
618

619 If a person and its affiliates own at least twenty ANDAs on the GDUFA Program Fee due date,
620 the person and its affiliates shall owe a large size operation GDUFA Program Fee.⁴⁰
621

622 See FDA’s GDUFA website for the current fiscal year’s fee amounts
623 (<https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>).
624

B. Single Fee for Applicant and its Affiliates

625
626 An applicant and its affiliates together will only incur one GDUFA Program Fee per year.
627 GDUFA II mandates that a “single fee shall be assessed” for an ANDA sponsor and its
628 affiliates.⁴¹ The ANDA sponsor who is responsible for submitting the affiliate information on
629 behalf of the company and its affiliates must submit complete information so that FDA will
630 assess one GDUFA Program Fee for the sponsor. If FDA finds an affiliation that was not
631 reported to the Agency, FDA will re-assess the fees for both the affiliate and parent company,
632 potentially resulting in an invoice if FDA finds that the firm should have paid a higher amount.
633
634

C. Submitting Information to FDA

635
636 Each person that owns an ANDA shall submit to the Secretary, by April 1 of each year, a list of
637 all ANDAs held by such person; except that, if an affiliate of such person also owns ANDAs, the
638 person or its affiliate must submit, on behalf of the person and its affiliates, a list identifying all
639 affiliates that own such applications and the ANDAs owned by the person and its affiliates.
640 Please see FDA’s GDUFA website
641 (<https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>) for more
642 information.
643

⁴⁰ See Section 744B(b)(2)(E) of the FD&C Act.

⁴¹ *Id.*

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D. Timing for Withdrawal of ANDAs

An ANDA shall be deemed not to be approved for purposes of the GDUFA Program Fee if the applicant has submitted a written request for withdrawal of approval of such ANDA by April 1 of the previous fiscal year. If such a request to withdraw an ANDA is made after April 1st, FDA may not be able to withdraw the approved ANDA by the October 1 due date for that fee and the applicant should expect that that ANDA will be counted as approved when determining which tier an applicant and its affiliates are placed.

X. DETERMINING AFFILIATION

When determining whether parties are affiliated, the critical factor is whether one party controls or has the power to control another entity, or if a third party has the power to control both entities.

FDA may contact the applicant to request additional information and clarification of the information asserted by the applicant. Examples of requested information include, but are not limited to the following:

- A copy of the applicant’s Articles of Incorporation and Bylaws;
- The applicant’s last annual statement to shareholders;
- A breakdown of entities that maintain ownership of the applicant’s company; and
- Identification of persons in leadership and management positions at the applicant’s company.

Occasionally, FDA finds entities affiliated with the applicant that the applicant did not identify as one of its affiliates. In such cases, FDA recommends that the applicant submit any agreements between an applicant and the other entities that demonstrate the nature of the relationship the applicant has with the entity.

FDA recognizes that some information provided by companies may be confidential. FDA will treat confidential commercial or financial information consistent with applicable federal laws and regulations.

XI. FAILURE TO PAY FEES

Failure to remit payment for user fees incurred pursuant to GDUFA II will result in certain penalties based on the type of fee. Outstanding user fees are an obligation to the U.S. government and the failure to pay fees may lead to collection activities by the government pursuant to applicable laws.

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A. Backlog Fees

Any person who owned an original ANDA that failed to pay the backlog fee was placed on a publicly available arrears list available at <https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>. FDA will not receive—within the meaning of section 505(j)(5)(A) of the FD&C Act (21 U.S.C. § 355(j)(5)(A))⁴²—a new ANDA or supplement submitted by that person, or any affiliate of that person, until the outstanding fee is paid.⁴³

B. DMF Fees

Unless the DMF fee is paid in full, the DMF will not be deemed available for reference. No generic drug submission referencing the DMF will be received unless the fee is paid and the DMF is deemed available for reference.

ANDA applicants that reference a DMF for which a fee is due but has not been paid will be provided notification of the DMF holder’s failure to satisfy the user fee obligation. If the DMF fee is not paid within 20 calendar days after notification, any generic drug submission referencing the DMF will not be received for user fee reasons and no refund of the fee will be allowed.⁴⁴

C. ANDA Filing Fees

If an applicant does not submit payment within 20 calendar days of the due date, its application or supplement to an application will be deemed incomplete on the date of submission and will not be received. So long as FDA finds that none of the disqualifications outlined in 21 CFR 314.101(d) and (e) apply, the application will be considered submitted as of the date all obligations are satisfied and the payments are received in full.⁴⁵

D. Facility Fees

There are several consequences for failure to pay a facility fee:

- No new ANDA or supplement submitted by the person responsible for paying the fee or that person’s affiliates will be received.

⁴² This provision references the “receipt” of ANDAs by FDA. The agency does an initial review of the application to determine whether it may be received. Receipt represents a threshold determination that the ANDA is sufficiently complete to permit a substantive review. 21 CFR 314.101(b). An application that is not received will not be reviewed substantively and will not be approved. References to receiving applications in this section of the guidance refer to receipt under this process.

⁴³ See Section 744B(g)(1) of the FD&C Act.

⁴⁴ See Section 744B(g)(2) of the FD&C Act.

⁴⁵ See Section 744B(g)(3) of the FD&C Act.

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- 723 • No new generic drug submission referencing the facility will be received until the fee is
724 paid.
725 • The facility will be placed on a publicly available arrears list if the fee is not fully paid
726 within 20 days of the due date.
727 • FDA will notify the referencing ANDA applicant of the facility’s failure to satisfy its user
728 fee obligations.

729
730 Furthermore, all FDFs or APIs manufactured in the non-paying facility and all FDFs containing
731 APIs manufactured in such a facility will be deemed misbranded. This means that it will be a
732 violation of federal law to ship these products in interstate commerce or to import them into the
733 United States. Such violations can result in prosecution of those responsible, injunctions, or
734 seizures of misbranded products. Products deemed misbranded are subject to being denied entry
735 into the United States.⁴⁶

736
737 Additionally, goal dates may not apply to applications that have already been received but that
738 reference facilities for which facility fees are owed.

E. GDUFA Program Fees

740
741
742 Failure to pay the GDUFA Program Fee within 20 calendar days of the GDUFA Program Fee
743 due date will result in the following penalties:

- 744
745 • Applicants that have not paid the GDUFA Program Fee will be placed on a publicly
746 available arrears list.
747 • Any ANDAs submitted by the applicant or an affiliate of that applicant will not be
748 received.
749 • All drugs marketed pursuant to ANDAs held by such applicant or an affiliate of that
750 applicant will be deemed misbranded.⁴⁷

751
752 These penalties apply until the GDUFA Program Fee is paid.

XII. PAYMENT INFORMATION AND PROCEDURES

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754
755
756 The payment process for GDUFA II is similar to the previous iteration of the program and other
757 FDA user fees. The FDA website contains instructions for paying the fees.

A. Payment Procedures for GDUFA Fees

- 758
759
760
761 • Those responsible for payment of fees enter required information on FDA’s User Fee
762 System to generate a GDUFA cover sheet.
763 • The cover sheet is designed to provide the minimum necessary information to determine

⁴⁶ See Section 744B(g)(4) of the FD&C Act.

⁴⁷ See Section 744B(g)(5) of the FD&C Act.

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- 764 if a person has satisfied all relevant user fee obligations.
765 • The cover sheet is submitted to FDA electronically generating a user fee payment
766 identification number (PIN) to assist in tracking payment.
767

768 Cover sheets should be submitted with generic drug submissions and DMFs. The Generic Drug
769 User Fee Cover Sheet and additional payment information is available on the GDUFA website
770 (<https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>).
771

B. Acceptable Forms of Payment

772
773
774 Payment must be made in U.S. currency drawn on a U.S. bank. Fee payers may pay online by
775 credit card or Automated Clearing House (ACH) electronic check or send payment by check,
776 bank draft, U.S. postal money order, or wire transfer.
777

C. Timely Payment of Fees

778
779
780 FDA's expectation is for full and timely payment of all GDUFA fees. Penalties associated with
781 non-payment, including, but not limited to, refusal to receive a generic drug submission and
782 failure of a DMF to be placed on a publicly available reference list, will apply until such
783 obligations are satisfied in full.
784

785 One entity may pay GDUFA fees on behalf of another entity. Those paying fees are responsible
786 for determining all financial institution transaction fees that may be deducted from a company's
787 authorized amount for payment to FDA. These include wire transfer and foreign exchange fees.
788

D. Refund Requests

789
790
791 FDA will only refund payments of fees made in error. If a fee was properly incurred, there will
792 be no refund of the payment.
793

794 To qualify for the return of a fee claimed to have been paid in error, a person shall submit to the
795 Secretary a written request justifying such return within 180 calendar days after such fee was
796 paid. The format for submitting refund requests is Form FDA 3913, attached as Appendix 1.
797 Form FDA 3913 is available on the internet at
798 <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.
799

800 FDA will not permit a refund if a written request is made past 180 calendar days from the date of
801 payment.
802

803 A written refund request should be submitted to the Division of User Fee Management and
804 Budget Formulation at CDERCollections@fda.hhs.gov.
805

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E. Non-Payment of GDUFA Fees

806
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808 Delinquent companies will receive an invoice from FDA detailing information on the user fee
809 incurred, the due date, and payment instructions.

810
811 If full payment is not received by the date specified on the invoice, interest will be charged at a
812 rate set by the U.S. Department of the Treasury. In addition, delinquent invoices will have a \$20
813 administrative fee assessed for each 30-day period that the invoice remains outstanding. A
814 penalty of 6 percent per year will be assessed on any invoices delinquent for more than 90 days,
815 in accordance with 45 CFR 30.18.

F. Cover Sheet for PET Manufacturers and Non-Commercial Government Entities

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817
818
819
820 PET drug manufacturers and State or Federal Government entities which sponsor or manufacture
821 drugs but do not distribute them commercially are excluded from payment of GDUFA fees.
822 However, FDA requests that all drug manufacturers, including generic PET manufacturers and
823 non-commercial government entities, complete a facility user fee coversheet in the user fee
824 system.

G. Waivers of and Reductions to GDUFA Fees

825
826
827
828 Waiver and reductions to GDUFA fees are generally not available. However, facilities that
829 qualify as CMOs only incur one-third of the facility FDF fee.

H. Arrears Lists

830
831
832
833 The backlog arrears list, GDUFA Program Fee arrears list, facility arrears list, and outstanding
834 facility fees—not on arrears list are available on the GDUFA website
835 (<https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>) and are updated
836 regularly.

837
838 FDA cannot receive generic drug submissions from sponsors or their affiliates until the sponsor
839 and its affiliates satisfy all outstanding user fee obligations. See the Definitions section (Section
840 III) above regarding affiliates for more information.

841
842 FDA will not notify sponsors before refusing to receive a submission.⁴⁸ Companies are in the
843 best position to monitor their business affiliates for compliance with GDUFA II. It is an
844 applicant's responsibility to ensure that its user fee obligations, as well as those of its affiliates,
845 are satisfied before submitting a new generic drug submission.

846

⁴⁸ See Section 744B(g) of the FD&C Act.

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847 If a company believes that its appearance on the arrears list is in error, it should contact the
848 Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov.
849 A concise rationale for why the facility should not be included on the arrears list should be
850 provided.

851

I. Submitting Generic Drug Submissions

852

853
854 A generic drug submission or Type II API DMF is deemed to be submitted to FDA on the
855 calendar day when the electronic submission arrives at FDA's electronic gateway, except when a
856 submission is made on a weekend, Federal holiday, or a day when the FDA office that will
857 review the submission is not otherwise open for business. In those cases, the submission will be
858 deemed to be submitted on the next day that office is open for business.

859

860 For a generic drug submission or Type II API DMF that is submitted in physical media form, the
861 date of submission will be the day it arrives at the appropriate designated FDA document room,
862 except when a submission arrives on a weekend or a day when the FDA office is not otherwise
863 open for business. In those cases, the submission will be deemed to be submitted on the next day
864 that office is open for business.

865

866 When a government-wide shutdown or closing of the relevant FDA office because of inclement
867 weather occurs, FDA is considered not open for business and will not receive generic drug
868 submissions until the next day that FDA is open for business.⁴⁹

869

870

XIII. APPEALS PROCESS

871

872

A. Reconsideration Request

873

874

875 If FDA fully or partially denies a request for a refund or reduction of user fees, the entity may
876 request reconsideration of that decision. A request for reconsideration should be made within 30
877 calendar days of the issuance of FDA's decision to fully or partially deny a request for a refund
878 or reduction of user fees.

879

880 FDA recommends that requests for reconsideration state the entity's reasons for believing that
881 the decision is in error and include any additional information, including updated financial
882 information, that is relevant to the entity's position. The Agency will issue a response upon
883 reconsideration, setting forth the basis for the decision.

884

⁴⁹ See guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*, available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm333969.pdf>.

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885 All requests for reconsiderations should be submitted via email to
886 CDERCollections@fda.hhs.gov and should be addressed to the following:

887
888 Division of User Fee Management and Budget Formulation
889 Attention: Division Director
890 Center for Drug Evaluation and Research

891
892 Alternatively, the entity can mail the request to FDA via the carrier of its choice. For the most
893 updated mailing address, visit the following FDA website:
894 <http://www.fda.gov/forindustry/userfees/genericdruguserfees/default.htm>.

895 896 **B. Appeal Request**

897
898 If a request is denied upon reconsideration, the entity may choose to appeal the denial. A request
899 for an appeal should be made within 30 calendar days of the issuance of FDA's decision to
900 affirm its denial of a request for a refund or reduction of user fees. The following information
901 should be included in the appeal:

- 902
- 903 • The original request
 - 904 • The denial of the request
 - 905 • The reconsideration request
 - 906 • The denial of the reconsideration request; and
 - 907 • A statement of the entity's belief that the prior conclusions were in error.
- 908

909 **No new information or analyses should be presented in the appeal request.** If new
910 information or analyses are presented in the appeal request, the appeal will not be accepted and
911 the matter will be referred back to the original deciding authority to consider the new
912 information or analyses.

913
914 All requests for appeals should be submitted to the Director of CDER's Office of Management
915 via CDERCollections@fda.hhs.gov and a copy should be submitted to the CDER Formal
916 Dispute Resolution Project Manager. The contact information can be found on the CDER
917 Formal Dispute Resolution Web page.⁵⁰ Alternatively, the entity can mail the request to FDA
918 via the carrier of its choice. For the most updated mailing address, visit the following FDA
919 website: <http://www.fda.gov/forindustry/userfees/genericdruguserfees/default.htm>.

920
921 After FDA reviews the information submitted in the appeal request, the Director of CDER's
922 Office of Management will issue a written decision on the entity's request.

923

⁵⁰ See

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/ucm444092.htm>.

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924 If the entity's appeal is denied at one management level, the entity can appeal the same matter to
925 the next higher management level in the center chain of command. A new request should be
926 submitted for each appeal to the next management level and should follow the process provided
927 in this guidance. If the sponsor has exhausted the center's management levels and remains
928 unsatisfied with the decision, the sponsor may request review of the matter by the Commissioner
929 of Food and Drugs (Commissioner) under 21 CFR 10.75(c). Requests for review by the
930 Commissioner should be submitted to FDA's Ombudsman, with copies provided to the centers.
931 Review of such matters by the Commissioner is discretionary.⁵¹

932
933

XIV. OTHER RESOURCES

934
935
936
937

The following guidance documents may be helpful:

- 938 • *Completeness Assessments for Type II API DMFs Under GDUFA*
939 (<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf>)
- 941 • *Self-Identification of Generic Drug Facilities, Sites, and Organizations*
942 (<https://www.fda.gov/downloads/drugs/guidances/ucm316672.pdf>)
- 943 • *Formal Dispute Resolution: Appeals Above the Division Level*, Revision 2 (September
944 2015)
945 (<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm343101.pdf>)

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950

Additional information is also available on the FDA User Fees web page. For any questions, please email the GDUFA User Fee staff at CDERCollections@fda.hhs.gov or call 301-796-7900.

⁵¹ See 40 FR 40682, 40693 (September 3, 1975); See 21 CFR 10.75.

User Fee Payment Refund Request

Section A: Organization Information

1. Date of Request (mm/dd/yyyy)

2. Organization Name

3. Organization Address

Address 1 (Street address. No P.O. Boxes allowed)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

State/Province/Region

Country

ZIP or Postal Code

4. Type of Vendor (Select applicable)

U.S. vendor Foreign vendor

5. TIN/EIN (Nine-digit number required for **all** U.S. vendors.) Without this entry, refund cannot be processed.

6. DUNS (Nine-digit number required for **all** foreign vendors. See instructions for additional information.) Without this entry, refund cannot be processed.

Information for U.S. vendors: To facilitate your request, visit <https://www.sam.gov/portal/public/SAM/> and register with Central Contractor Registration (CCR). CCR electronically validates registrant information and shares the encrypted data securely with the FDA. For questions about CCR, call (334) 206-7828.

Section B: Contact Information

7. Contact Name

8. Contact Title/Position

9. Contact Phone Number (Include area code)

10. Contact Email Address

Section C: Payment Information

11. Payment Amount

12. Payment Reference Number

13. PIN or Invoice Number

14. Refund Amount

15. Is this a FURLS refund request? (See instructions for more information.)

Yes No (Proceed to field 16)

(a) FURLS Request Type

Used PIN Unused PIN (Proceed to field 16)

(b) Registration or Owner/Operator Number

(c) Why did your facility originally pay the fee?

(d) Why do you believe your facility is not required to pay the fee?

(e) List all activities performed at your facility

(Section C continued, next page)

Section C: Payment Information (Continued)

15. Is this a FURLS refund request? (Continued)

(f) List all products manufactured at your facility

16. Reason for Request (Please explain)

17. **ACKNOWLEDGEMENT:** By signing this document I acknowledge that I am the official listed on this form, authorized to execute this request on behalf of my organization. Any questions regarding this request can be directed to me via the contact information provided.

18. Signature

Date of Signature (mm/dd/yyyy)

To enable the signature field, please fill out all prior required fields. For a list of required fields which have not yet been filled out, please click here.

Section D: FDA Acknowledgement

19. FDA Received Date (mm/dd/yyyy)

20. Center Decision

Approved Denied

21. If Denied, State Reason

22. Decision Date (mm/dd/yyyy)

23. Center Contact Name

OFM Use Only

24. Request Executed?

Yes No

25. If No, State Reason

26. Final Action

Completed – Refunded Completed – Not Refunded

27. Date of Final Action (mm/dd/yyyy)

28. OFM Contact Name

Instructions for Completing User Fee Payment Refund Request – Form FDA 3913

Form FDA 3913 is to be completed online at <http://www.fda.gov/forindustry/userfees/default.htm> and is to be used when requesting the transfer of user fee payments received by the FDA. If you need assistance in completing this form contact the User Fee Helpdesk via phone at (301) 796-7200 or email userfees@fda.gov.

Section A: Payment Information

1. **Date of Request:** Enter calendar date the form is being completed.
2. **Organization Name:** This is name of the organization submitting the request.
3. **Organization Address:** Enter the following elements of the organization's address.

Address 1 – Enter organization's physical street address where the refund is to be sent. No P.O. Boxes are allowed.

Address 2 – As needed, enter apartment, suite, unit, building, floor, etc.

City – Enter the city where organization is located.

State/Province/Region – Enter the state, province or region where organization is located.

Country – Enter country where organization is located.

ZIP or Postal Code – Enter zip code or postal code of the organization's location.

Instructions (Continued)

4. **Type of Vendor:** Select the appropriate box to indicate whether the organization is a U.S. or foreign vendor.
5. **TIN/EIN:** (U.S. vendor only) Enter organization's nine-digit federal Taxpayer Identification Number (TIN) or Employer Identification Number (EIN). Without this entry, the refund request cannot be processed.
6. **DUNS:** (Foreign vendor only) Enter organization's nine-digit Dun & Bradstreet Data Universal Numbering System (DUNS) number. If you do not know your DUNS number or need to request one, visit www.dnb.com or call (800) 234-3867. Without this entry the refund cannot be processed.

Section B: Contact Information

7. **Contact Name:** Enter the name of the person requesting the refund.
8. **Contact Title/Position:** Enter the position/title of the person requesting the refund.
9. **Contact Phone Number:** Enter the phone number of the person requesting the refund.
10. **Contact Email Address:** Enter the email address of the person requesting the refund.

Section C: Payment Information

11. **Payment Amount:** Enter the amount (in U.S. Dollars) of the original payment issued to the FDA.
12. **Payment Reference Number:** If payment was remitted via check, money order or bank draft, enter the check or money order number; if made electronically via Automated Clearing House (ACH) or credit card, enter the confirmation number; if made via wire transfer, enter the trace or Input Message Accountability Data (IMAD) number.
13. **PIN or Invoice Number:** Enter the Payment Identification Number (PIN) or invoice number where payment was applied.
14. **Refund Amount:** Enter the amount (in U.S. Dollars) that is to be refunded.
15. **Is this a FURLS refund request?** If request is for fees paid for registration within the FDA Unified Registration and Listing System (FURLS), check the appropriate box. If response is "Yes", complete fields (a) through (f). If response is "No", proceed to field 16.
(a) FURLS Request Type – Check "Used PIN" if PIN was used to register your facility with FDA's

Center for Devices and Radiological Health (CDRH). Check "Unused PIN" if PIN was not used to register, and proceed to field 16.

(b) Registration or Owner/Operator Number – Enter FURLS registration or owner/operator number.

(c) Why did your facility originally pay the fee? – Provide reason why the user fee was paid.

(d) Why do you believe your facility is not required to pay the fee? – Provide reason why the facility should not be required to pay the fee.

(e) List all activities performed at your facility – Provide list of all activities currently performed at your facility (i.e. manufacture medical device, contract sterilizer, etc.).

(f) List all products manufactured at your facility – Provide list of all products associated with each activity.

16. **Reason for Request:** Provide a brief description of why refund is being requested.
17. **Acknowledgement:** Review acknowledgment, confirming that you are the authorized representative listed on this form and have provided valid contact information in the event that there are questions pertaining to the request.
18. **Signature:** Place signature of listed authorizing official here.
Date of Signature – Date document is signed by authorizing official.

Section D: FDA Acknowledgement

This section is for FDA use only. An FDA representative will fill out the following items:

19. **FDA Received Date:** Enter date that request was received by FDA.
20. **Center Decision:** Check appropriate box, indicating if request was approved or denied.
21. **If Denied, State Reason:** If response to field 20 was "Denied", provide reason.
22. **Decision Date:** Enter date decision was made.
23. **Center Contact Name:** Enter name of the Center's action officer.
24. **Request Executed:** Check the appropriate box, indicating if request was executed.
25. **If No, State Reason:** If response to field 24 was "No", provide reason.

Instructions (Continued)

26. **Final Action:** Check the appropriate box, indicating if request was refunded or not refunded.

27. **Date of Final Action:** Enter date that final action was taken on request.

28. **OFM Contact Name:** Enter name of the OFM action officer.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

User Fee Payment Transfer Request

Section A: Payment Information

1. Date of Request (*mm/dd/yyyy*)

2. Payment Amount

3. Payment Reference Number

4. Transfer Funds From

5. Transfer Funds To

6. Transfer Amount

7. Transfer Reason (*Please explain*)

Section B: Contact Information

8. Organization Name

9. Organization Address

Address 1 (*Street address. No P.O. Boxes allowed*)

Address 2 (*Apartment, suite, unit, building, floor, etc.*)

City

State/Province/Region

Country

ZIP or Postal Code

10. Contact Name

11. Contact Title/Position

12. Contact Phone Number (*Include area code*)

13. Contact Email Address

14. **ACKNOWLEDGEMENT: By signing this document I acknowledge that I am the official listed on this form, authorized to execute this request on behalf of my organization. Any questions regarding this request can be directed to me via the contact information provided.**

15. Signature

Date of Signature (*mm/dd/yyyy*)

To enable the signature field, please fill out all prior required fields. For a list of required fields which have not yet been filled out, please [click here](#).

Section C: FDA Acknowledgement

16. FDA Received Date (*mm/dd/yyyy*)

17. Center Decision

Approved

Denied

18. If Denied, State Reason

19. Decision Date (*mm/dd/yyyy*)

20. Center Contact Name

(FDA Acknowledgement continued, next page)

Section C: FDA Acknowledgement (Continued)

OFM Use Only

21. Request Executed?
 Yes No

22. If No, State Reason

23. Final Action
 Completed – Transferred Completed – Not Transferred

24. Date of Final Action (mm/dd/yyyy)

25. OFM Contact Name

Instructions for Completing User Fee Payment Transfer Request – Form FDA 3914

Form FDA 3914 is to be completed online at <http://www.fda.gov/forindustry/userfees/default.htm> and is to be used when requesting the transfer of user fee payments received by the FDA. If you need assistance in completing the form contact the User Fee Helpdesk via phone at (301) 796-7200 or email userfees@fda.gov.

Section A: Payment Information

1. **Date of Request:** Enter calendar date the form is being completed.
2. **Payment Amount:** Enter the amount (in U.S. Dollars) of the original payment.
3. **Payment Reference Number:** If payment was remitted via check, money order or bank draft, enter the check or money order number; if made electronically via Automated Clearing House (ACH) or credit card, enter the confirmation number; if made via wire transfer, enter the trace or Input Message Accountability Data (IMAD) number.
4. **Transfer Funds From:** Enter the Payment Identification Number (PIN) or invoice number where payment is coming from.
5. **Transfer Funds To:** Enter the PIN or invoice number where payment is to be applied.
6. **Transfer Amount:** Enter the amount (in U.S. Dollars) that is to be transferred.
7. **Transfer Reason:** Provide a brief description of why funds are being transferred.

Section B: Contact Information

8. **Organization Name:** This is name of the organization listed on the cover sheet or invoice. Entry should match both old and new cover sheets or invoices as listed in items 4 and 5.
9. **Organization Address:** Enter the following elements of the organization address.

Address 1 – Enter organization's physical street address. *No P.O. Boxes are allowed.*

Address 2 – As needed, enter apartment, suite, unit, building, floor, etc.

City – Enter the city where organization is located.

State/Province/Region – Enter the state, province or region where organization is located.

Country – Enter country where organization is located.

ZIP or Postal Code – Enter zip code or postal code of the organization's location.

10. **Contact Name:** Enter the name of the person requesting the transfer.
11. **Contact Title/Position:** Enter the position/title of the person requesting the transfer.
12. **Contact Phone Number:** Enter the phone number of the person requesting the transfer.
13. **Contact Email Address:** Enter the email address of the person requesting the transfer.
14. **Acknowledgement:** Review acknowledgment, confirming that you are the authorized representative listed on this form and have provided valid contact information in the event that there are questions pertaining to the request.
15. **Signature:** Place signature of listed authorizing official here.

Date of Signature – Date document is signed by authorizing official.

Section C: FDA Acknowledgement

This section is for FDA use only. An FDA representative will fill out the following items:

16. **FDA Received Date:** Enter date that request was received by FDA.

Instructions (Continued)

- | | |
|--|--|
| <p>17. Center Decision: Check appropriate box, indicating if request was approved or denied.</p> <p>18. If Denied, State Reason: If response to field 17 was “Denied”, provide reason.</p> <p>19. Decision Date: Enter date decision was made.</p> <p>20. Center Contact Name: Enter name of the Center’s action officer.</p> <p>21. Request Executed: Check the appropriate box, indicating if request was executed.</p> | <p>22. If No, State Reason: If response to field 21 was “No”, provide reason.</p> <p>23. Final Action: Check the appropriate box, indicating if request was transferred or not transferred.</p> <p>24. Date of Final Action: Enter date that final action was taken on request.</p> <p>25. OFM Contact Name: Enter name of the OFM action officer.</p> |
|--|--|

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”