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# Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products Guidance for Industry

## *DRAFT GUIDANCE*

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

**June 2018  
User Fees**

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# Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products Guidance for Industry

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1                   **Prescription Drug User Fee Act Waivers, Reductions,**  
2                   **and Refunds for Drug and Biological Products**  
3                   **Guidance for Industry<sup>1</sup>**  
4  
5

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7 This draft guidance, when finalized, will represent the current thinking of the Food and Drug  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 staff responsible  
11 for this guidance as listed on the title page.  
12

13  
14  
15 **I. INTRODUCTION**  
16

17 This guidance provides recommendations to applicants regarding requests for waivers, refunds,  
18 and reductions of user fees assessed under sections 735 and 736 of the Federal Food, Drug, and  
19 Cosmetic Act (the FD&C Act) for drugs, including biological products.<sup>2</sup> This guidance is a  
20 revision of the guidance for industry entitled *User Fee Waivers, Reductions, and Refunds for*  
21 *Drug and Biological Products*, issued in September 2011.  
22

23 This revised draft guidance describes (1) the types of waivers, refunds, and reductions available  
24 under the user fee provisions of the FD&C Act, (2) the procedures for requesting waivers,  
25 refunds, or reductions, and (3) the process for requesting a reconsideration or appeal of an FDA  
26 decision. The draft guidance also provides clarification on related issues such as user fee  
27 exemptions for orphan drugs.  
28

29 In general, FDA's guidance documents do not establish legally enforceable responsibilities.  
30 Instead, guidances describe the Agency's current thinking on a topic and should be viewed only  
31 as recommendations, unless specific regulatory or statutory requirements are cited. The use of  
32 the word *should* in Agency guidances means that something is suggested or recommended, but  
33 not required.  
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<sup>1</sup> This guidance has been prepared by the Division of User Fee Management and Budget Formulation, Office of Management, Center for Drug Evaluation and Research, in consultation with the Center for Biologics Evaluation and Research.

<sup>2</sup> For the purposes of this document, unless otherwise specified, references to "drugs" or "drug products" include drugs submitted under section 505(b) of the FD&C Act and biological products licensed under section 351(a) of the PHS Act, other than biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

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### 38 **II. BACKGROUND**

39  
40 The Prescription Drug User Fee Act of 1992 (PDUFA I) amended the FD&C Act, and authorized  
41 FDA to collect user fees for 5 years from companies that produce certain human drug and  
42 biological products. PDUFA must be reauthorized every 5 years, and has been reauthorized 5  
43 times since PDUFA I, most recently in 2017 under Title I of the FDA Reauthorization Act of  
44 2017 (PDUFA VI).

45  
46 PDUFA VI authorizes FDA to assess application fees for certain human drug and biological  
47 product applications when those applications are submitted. In addition, PDUFA VI authorizes  
48 FDA to assess annual prescription drug program fees (program fees) for certain approved drug  
49 and biological products.<sup>3</sup>

50  
51 Because of the way the user fee program is structured in the FD&C Act, the total amount FDA  
52 collects in user fees is independent of the number of waivers or reductions in fees that are  
53 granted. Target revenues are established in accordance with a statutory formula, and the amount  
54 of each type of fee (application and program) is determined based on historical data of how many  
55 applications and products were assessed fees in the previous fiscal years. Therefore, the number  
56 of waivers, refunds and reductions granted in a fiscal year is factored into the statutory formula  
57 and may result in an increase or decrease in application and program fees for the following year  
58 to meet the annual statutory revenue targets.

### 59 60 61 **III. DEFINITIONS**

62  
63 For purposes of this guidance:

- 64
- 65 • The term *affiliate* means a business entity that has a relationship with a second business  
66 entity if, directly or indirectly, (A) one business entity controls, or has the power to  
67 control, the other business entity; or (B) a third party controls, or has the power to  
68 control, both of the business entities.<sup>4</sup>
  - 69
  - 70 • The term *applicant* means the owner, holder, or sponsor of a new drug application  
71 (NDA) or biologics license application (BLA), submitted under section 351(a) of the  
72 Public Health Service (PHS) Act.
  - 73
  - 74 • The term *application* includes both NDAs, submitted under section 505 of the FD&C  
75 Act, and BLAs, submitted under section 351(a) of the PHS Act.
  - 76
  - 77 • The term *drug* includes drug and biological products.

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<sup>3</sup> Information on application and program fees, including fee rates, PDUFA goals, and other user fee related issues can be found on FDA's PDUFA website:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>.

<sup>4</sup> Section 735(11) of the FD&C Act.

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- 78 • The term **human drug application** means an application for (1) approval of a new drug  
79 submitted under section 505(b) of the FD&C Act or (2) licensure of a biological product  
80 under section 351(a) of the PHS Act.<sup>5</sup> For purposes of this guidance, the term **human**  
81 **drug application** does not include the following:  
82
- 83 • A supplement to such an application;
  - 84 • An application with respect to whole blood or a blood component for  
85 transfusion;
  - 86 • An application with respect to a bovine blood product for topical application  
87 licensed before September 1, 1992;
  - 88 • An application for an allergenic extract product;
  - 89 • An in vitro diagnostic biologic product licensed under section 351 of the PHS  
90 Act;
  - 91 • An application with respect to a large volume parenteral drug product  
92 approved before September 1, 1992;
  - 93 • An application for a licensure of a biological product for further  
94 manufacturing use only; and,
  - 95 • An application submitted by a State or Federal Government entity for a drug  
96 that is not distributed commercially.<sup>6</sup>  
97
- 98 • The term **person** means the person subject to fees and includes any affiliates of that  
99 person.<sup>7</sup> The term **person** includes an individual, partnership, corporation, and  
100 association.<sup>8</sup> This document will also use the term **person** when referring to an applicant.  
101
- 102 • The term **prescription drug product** means a specific strength or potency of a drug in  
103 final dosage form --  
104
- 105 • for which a human drug application has been approved,
  - 106 • which may be dispensed only by prescription under section 503(b) of the FD&C Act,  
107 and
  - 108 • which is on the list of products described in section 505(j)(7)(A) of the FD&C Act  
109 (not including the discontinued section of such list) or is on a list created and  
110 maintained by FDA of products approved under human drug applications under  
111 section 351(a) of the PHS Act (not including the discontinued section of such list).<sup>9</sup>  
112
- 113 Such term does not include:
- 114 • Whole blood or a blood component for transfusion;
  - 115

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<sup>5</sup> Section 735(1) of the FD&C Act.

<sup>6</sup> Id.

<sup>7</sup> Section 735(9) of the FD&C Act.

<sup>8</sup> Section 201(e) of the FD&C Act.

<sup>9</sup> Section 735(3) of the FD&C Act.

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- 116 • A bovine blood product for topical application licensed before September 1, 1992;
- 117 • An allergenic extract product;
- 118 • An in vitro diagnostic biologic product licensed under section 351 of the PHS Act;
- 119 • A biological product that is licensed for further manufacturing use only; and
- 120 • A drug that is not distributed commercially and is the subject of an application or
- 121 supplement submitted by a State or Federal Government entity.<sup>10</sup>
- 122
- 123 • The term ***supplement*** means a request to FDA to approve a change in a human drug
- 124 application that has been approved.<sup>11</sup>
- 125
- 126 • The term ***financial resources*** means the current financial assets, including cash and any
- 127 other income available other than cash in the form of liquid securities and credit lines, of
- 128 an applicant and its affiliates. See section IV.C. below for more information.
- 129
- 130

### **IV. TYPES OF WAIVERS AND REDUCTIONS**

131 According to section 736(d) of the FD&C Act, FDA will grant to an applicant a waiver of or  
132 reduction in one or more user fees assessed under section 736(a) of the FD&C Act where it finds  
133 that:

- 137 • A waiver or reduction is necessary to protect the public health.
- 138
- 139 • The assessment of the fee would present a significant barrier to innovation because of
- 140 limited resources available to the person or other circumstances.
- 141
- 142 • The applicant is a small business submitting its first human drug application to FDA for
- 143 review.
- 144

145 Sections IV.A through IV.C below describe FDA’s considerations for each type of waiver.<sup>12</sup>

---

<sup>10</sup> Section 735(3) of the FD&C Act.

<sup>11</sup> Section 735(2) of the FD&C Act.

<sup>12</sup> There are three additional special circumstances that may affect an applicant’s eligibility for waivers or reductions under the public health and barrier to innovation waiver provision:

(1) for applicants participating in the President’s Emergency Plan for AIDS Relief (PEPFAR), see guidance for industry, *User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR*;

(2) for applicants submitting combination products under 21 Code of Federal Regulations 3.2(e), see guidance for industry, *Application User Fees for Combination Products*; and,

(3) for applicants submitting applications for certain types of positron emission tomography (PET) drugs (specifically, FDG F 18 injection, ammonia N 13 injection, and sodium fluoride F 18injection), see 21 FR 12999, 13004 (Mar. 10, 2000), and guidance for industry, *FDA Oversight of PET Drug Products: Questions and Answers*. Please note that the waivers for these PET drugs only apply to application fees; applicants who would like program fees waived may request a public health or barrier-to-innovation waiver, as is further described in this guidance. Any applicant submitting an application that may present these special circumstances should consult the relevant guidance and statutory provisions. FDA updates guidances periodically. To make sure you have the most recent version of a guidance, visit the FDA Drugs guidance website at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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### 146 **A. Public Health**

147  
148 Under section 736(d)(1)(A) of the FD&C Act, an applicant may qualify for a waiver or reduction  
149 in application or program fees if the waiver or reduction is necessary to protect the public health.  
150 Under this provision, FDA considers the following questions in determining whether to grant a  
151 public health waiver or reduction in user fees:

- 152
- 153 • Does the product protect the public health?
  - 154
  - 155 • Is the waiver or reduction ***necessary*** to continue an activity that protects the public  
156 health?
  - 157

158 Applicants should address both of these questions when applying for a public health waiver or  
159 reduction in fees.

#### 160 *1. Does the product protect the public health?*

161  
162 For user fee purposes, a product that has been approved for marketing in the United States is not  
163 automatically deemed to be a product that protects the public health. In evaluating whether a  
164 product protects the public health, the Agency generally intends to ask the following questions:

- 165
- 166 • Is the drug product a significant improvement (or does it have the potential to be a  
167 significant improvement if the drug product is not yet approved) compared to other  
168 marketed products, including other dosage forms or routes of administration and non-  
169 drug products or therapies?
  - 170
  - 171
  - 172 • Are there other treatment alternatives in the U.S. market? The existence of comparable  
173 treatment alternatives would weigh against a determination that a product is necessary to  
174 protect the public health.
  - 175
  - 176 • Has the drug product been designated as a priority drug, accepted into one of FDA's  
177 expedited programs for serious conditions,<sup>13</sup> granted fast track status,<sup>14</sup> or determined to  
178 be a new molecular entity? Affirmative answers to these questions usually indicate that a  
179 product protects the public health.
  - 180

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<sup>13</sup> Further information regarding priority drugs can be found in the guidance for industry, *Expedited Programs for Serious Conditions – Drugs and Biologics*, available at <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>, and in CDER's Manual of Policies and Procedures (MAPP) 6020.3R, *Review Designation Policy: Priority (P) and Standard (S)*. MAPP 6020.3R is available at <https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm082000.pdf>.

<sup>14</sup> Further information regarding fast track status is available at <https://www.fda.gov/forpatients/approvals/fast/ucm20041766.htm>.



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- 181 • Does the drug product demonstrate an increased effectiveness in the treatment,  
182 prevention, or diagnosis of disease?  
183
- 184 • Does it eliminate or substantially reduce a treatment-limiting drug reaction?  
185
- 186 • Does the drug product enhance patient adherence to treatment?  
187
- 188 • Has the drug product shown potential evidence of safety and effectiveness for a new or  
189 underserved subpopulation (e.g., treatment for a drug resistant microbe or response to a  
190 homeland security concern)?  
191
- 192 • Is the drug product intended for the diagnosis or treatment of a serious or life-threatening  
193 condition?  
194
- 195 • Does the drug product address unmet medical needs or demonstrate the potential to do  
196 so?  
197
- 198 • Is the product designated as a drug for a rare disease or condition under section 526 of the  
199 FD&C Act (i.e., does it have an orphan designation)?  
200
- 201 • If the drug product is approved, is the product recognized as an effective treatment option  
202 that significantly impacts the public health?  
203
- 204 • If the product is approved, is it available to the public? There is no benefit to the public  
205 health if a product is not made available to the public.<sup>15</sup>  
206
- 207 2. *Is the waiver or reduction necessary to continue an activity that protects the public*  
208 *health?*  
209

210 To determine whether a waiver or reduction in user fees is necessary to continue an activity that  
211 protects the public health, the Agency considers not only the benefit of the activity to the public  
212 health, but also whether the waiver or reduction is necessary. The legislative history of PDUFA  
213 I indicates that FDA may waive or reduce fees unless such a waiver or reduction is not necessary  
214 to protect the public health, or it is apparent that the fee will not be a disincentive to innovation.<sup>16</sup>  
215 It also indicates that FDA should consider the “limited resources” of the applicant when  
216 evaluating a request for a fee waiver or reduction under section 736(d).<sup>17</sup> Therefore, the Agency  
217 believes that a financial test is appropriate for the public health waiver provision. The Agency  
218 considers the relationship between current liabilities and the financial resources of the applicant,  
219 including affiliates, requesting the waiver or reduction. The financial considerations are  
220 discussed in section IV.C below.

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<sup>15</sup> FDA would consider products stockpiled for homeland security concerns as available to the public for user fee waiver purposes.

<sup>16</sup> See House Report 102-895 (1992) at 17; 138 Cong. Rec. S. 17239 (Oct. 7, 1992).

<sup>17</sup> Id.

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### 222 **B. Barrier to Innovation**

223

224 Under section 736(d)(1)(B) of the FD&C Act, an applicant may qualify for a waiver or reduction  
225 in application or program fees when the assessment of the fees would present a significant  
226 barrier to innovation because of limited resources available to the applicant or other  
227 circumstances. Under this provision, FDA considers the following questions in deciding whether  
228 to grant a barrier-to-innovation waiver:

229

230 • Is the product or other products or technologies under development by the applicant  
231 innovative?

232

233 • Would the fee(s) be a *significant barrier* to the applicant's ability to develop,  
234 manufacture, or market innovative products or to pursue innovative technology?

235

236 To qualify for a waiver or reduction in user fees under this provision, an applicant should address  
237 both questions.

238

239 *1. Is the product innovative or is the company pursuing other innovative drug products*  
240 *or technologies?*

241

242 A product that has been approved for marketing in the United States is not automatically deemed  
243 to be innovative for user fee purposes. In evaluating requests for barrier-to-innovation user fee  
244 waivers or reductions, the Agency generally intends to consider the following questions:

245

246 • Does the drug product or technology demonstrate advanced “breakthrough” research,  
247 new, progressive methods, and/or forward thinking in the treatment or diagnosis of  
248 disease, or does it have the potential to be at the forefront of new medical technology?

249

250 • Are there other treatment alternatives available? The existence of comparable  
251 alternatives would weigh against a determination that a product is innovative.

252

253 • Does the drug product or technology introduce a unique or superior method for  
254 diagnosing, curing, mitigating, treating, or preventing a disease, or for affecting a  
255 structure or function of the body?

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- 278
- Has the drug product been designated as a priority drug, accepted into one of FDA’s expedited programs for serious conditions,<sup>18</sup> granted fast track status,<sup>19</sup> or determined to be a new molecular entity?
  - Does the applicant have an *active* investigational new drug application (IND) under which the applicant is evaluating a potentially unique or superior method for diagnosing, curing, mitigating, treating, or preventing a disease, or for affecting a structure or function of the body? To determine whether an applicant’s IND would be considered *active*, the Agency may consider the following:
    - Is the applicant currently conducting a clinical trial for the investigational drug?<sup>20</sup>
    - Has the applicant recently participated in meetings and discussions with FDA about the IND progress?
    - Is the applicant actively developing the investigational drug? Does the applicant detail such development in its IND annual report?
  - Has the applicant recently received a Federal grant for innovation? An example of a Federal grant program that may qualify as innovative is the National Institutes of Health’s Small Business Innovative Research Program.
2. *Does the fee create a significant barrier to the applicant’s ability to develop, manufacture, or market innovative products or to pursue innovative technology?*

279 To determine whether a fee would be a significant barrier to an applicant’s ability to develop,  
280 manufacture, or market innovative products or to pursue innovative technology, the Agency  
281 considers the relationship between the current liabilities and financial resources of the applicant  
282 and its affiliates. The financial considerations are discussed below.  
283

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<sup>18</sup> Further information regarding priority drugs can be found in the guidance for industry, *Expedited Programs for Serious Conditions – Drugs and Biologics*, available at <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>, and in CDER’s MAPP 6020.3R, *Review Designation Policy: Priority (P) and Standard (S)*. MAPP 6020.3R is available at <https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm082000.pdf>.

<sup>19</sup> Further information regarding fast track status is available on the internet at <https://www.fda.gov/forpatients/approvals/fast/ucm20041766.htm>.

<sup>20</sup> FDA may use any available information, including but not limited to ClinicalTrials.gov, to determine whether the applicant is currently conducting a clinical trial.

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### 284 **C. Financial Considerations for Public Health and Barrier-to-Innovation Waivers and** 285 **Reductions**

#### 286 287 *1. Financial Resources of the Applicant and Affiliates*

288  
289 When evaluating requests for waivers or reductions in user fees under the public health or  
290 barrier-to-innovation provisions, the Agency considers the financial resources of the applicant  
291 and its affiliates.

292  
293 Section 736(d)(2) of the FD&C Act states that, in determining whether to grant a waiver or  
294 reduction in a user fee, FDA shall consider only the circumstances and financial resources of the  
295 applicant and any affiliate of the applicant. Under the FD&C Act, the applicant is the person<sup>21</sup>  
296 who is responsible for payment of the fees and the person who must qualify for a waiver or  
297 reduction in user fees.<sup>22</sup> Accordingly, the statute does not allow persons other than those legally  
298 subject to user fees, such as a distributor that is not an affiliate, to qualify for or receive waivers  
299 or reductions of user fees.

#### 300 301 *2. Consideration of Limited Financial Resources*

302  
303 The limited financial resources of an applicant and its affiliates are an important indicator of  
304 whether user fees are a barrier to innovation or a waiver or reduction is necessary to protect the  
305 public health. Based on over 25 years of experience in implementing the user fee program, FDA  
306 has determined that most applicants that, including the resources of its affiliates, have financial  
307 resources of less than \$20 million of working capital are those least able to pay the fees.  
308 Therefore, the Agency generally intends to use \$20 million as its marker for evaluating whether  
309 an applicant and its affiliates have limited resources such that a waiver or reduction is *necessary*  
310 to protect the public health and whether the fees are a *significant barrier* to innovation. An  
311 applicant with \$20 million or more in financial resources, including the financial resources of  
312 affiliates, generally will not be considered to have limited resources for user fee purposes.

313  
314 FDA generally intends to consider the working capital of an applicant and its affiliates to  
315 determine whether the applicant has limited financial resources. Working capital is an objective  
316 measure of the resources available to the applicant and is defined by generally accepted  
317 accounting principles. To calculate working capital, FDA intends to review current assets and  
318 current liabilities of applicants and their affiliates to determine if an applicant has limited  
319 financial resources. Net proceeds that increase the cash flow of an applicant and affiliates are  
320 also an important factor in determining whether the applicant and its affiliates have limited  
321 financial resources. FDA recommends that applicants provide financial information according to  
322 the fiscal year, which begins October 1 and ends September 30. If an applicant's financial  
323 records are not organized by the U.S. government's fiscal year, an applicant may submit  
324 financial information from the 12 months preceding the date of the waiver request. Section  
325 VI.C. provides more information on the type of documentation applicants may submit to support  
326 its assertions of its limited resources.

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<sup>21</sup> Under section 735(9) of the FD&C Act, *person* includes an affiliate thereof.

<sup>22</sup> See sections 736(a)(1), 736(a) (2), and 736(d) of the FD&C Act.

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327  
328 FDA does not intend to deduct marketing costs when calculating an applicant’s working capital.  
329 Because even a very large applicant may have operating losses, FDA does not intend to consider  
330 lack of profitability as evidence of limited resources. The Agency also does not intend to  
331 consider product sales figures to be evidence of limited resources, because even a large and  
332 profitable company can have low sales figures for an individual product, but not need a waiver to  
333 continue an activity that is necessary to protect the public health or because the fees would  
334 present a significant barrier to innovation.

335  
336 FDA considers the financial resources of applicants that are State or Federal government entities  
337 differently. The Agency generally intends to consider State or Federal government entities with  
338 less than \$20 million in total annual revenues ***from the sale of drugs*** to have limited resources  
339 for user fee purposes. A government entity is able to devote only a small amount of money to  
340 drug development activities relative to the entity’s budget and the total State or Federal budget.  
341 In addition, government entities generally receive only a small amount of revenue from  
342 commercial distribution of a drug, as compared with total revenues. FDA believes that Congress  
343 intended to minimize the burden on State and Federal government entities by focusing attention  
344 on their drug development revenues, not the overall revenues of the entity or the State or Federal  
345 government.<sup>23</sup> Section V.B. provides information on exemptions from application and program  
346 fees for State or Federal government entities that do not distribute commercially.

### **D. Small Business**

347  
348  
349 Under section 736(d)(1)(C) of the FD&C Act, an applicant is eligible for a waiver of the  
350 ***application fee*** if the applicant is a small business submitting its first human drug application to  
351 the Agency for review and does not have another product approved under a human drug  
352 application and introduced or delivered for introduction into interstate commerce.<sup>24</sup>

353  
354 To qualify for a small business waiver of the application fee, an applicant must:

- 355  
356 • Employ fewer than 500 employees, including employees of affiliates;<sup>25</sup>
- 357  
358 • Not have a drug product that has been approved under a human drug application and  
359 introduced or delivered for introduction into interstate commerce;<sup>26</sup> and
- 360  
361 • Be submitting its first human drug application, including its affiliates.<sup>27</sup>
- 362  
363

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<sup>23</sup> For example, the FD&C Act exempts a State or Federal government entity from application and program fees for a drug product that is not distributed commercially. Sections 735(1) and (3) of the FD&C Act.

<sup>24</sup> There is no specific provision in the FD&C Act for a waiver or reduction of program fees for small businesses. However, small businesses may apply for a waiver or reduction of program fees through the public health or barrier-to-innovation waiver provisions. See discussions in sections IV.A-IV.C above.

<sup>25</sup> Section 736(d)(3)(A) of the FD&C Act.

<sup>26</sup> *Id.*

<sup>27</sup> Section 736(d)(1)(C) of the FD&C Act.

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### 364 *1. Small Business Waiver and Refund Requests*

365  
366 To qualify for a small business waiver of the application fee, an applicant should submit to FDA  
367 Form FDA 3971, attached as Appendix 1. If an applicant submitted an NDA or BLA with a  
368 payment and would like to request a small business waiver and refund, the applicant should  
369 submit Form FDA 3971 to request the refund within 180 calendar days of when the application  
370 fee is due. Section VI.C provides further information about Form FDA 3971 and the waiver  
371 request process.

372  
373 FDA recognizes that some information provided by companies may be confidential. FDA will  
374 treat confidential commercial or financial information consistent with applicable federal laws  
375 and regulations (see section IX).

### 376 *2. Expiration Date of the Small Business Waiver*

377  
378 If a small business waiver is granted, the applicant should submit its human drug application  
379 within 1 year after the date of the small business determination since circumstances supporting a  
380 small business waiver can change rapidly. For example, an applicant could merge with a larger  
381 company and therefore no longer be considered a small business. Similarly, an applicant could  
382 purchase an NDA from an unaffiliated company and, therefore, would have a drug product that  
383 has been approved under a human drug application and introduced into or delivered for  
384 introduction into interstate commerce.

385  
386 If an applicant is granted a small business waiver and is unable to submit the application within 1  
387 year of the determination, the applicant should request a new small business waiver by following  
388 the instructions provided in section VI.C. The Agency generally intends to examine the newly  
389 submitted information to confirm that the applicant is still eligible for a small business waiver.

### 392 *3. Small Business Waivers of Application Fees for Future Human Drug Applications*

393  
394 After an applicant or its affiliate is granted a small business waiver and submits its first human  
395 drug application, the applicant cannot receive another small business waiver. That means that  
396 the applicant or its affiliate is not eligible to receive a small business waiver for any subsequent  
397 human drug application, even if the first application is withdrawn or refused for filing.<sup>28</sup> An  
398 applicant that received a small business waiver for an application that was later refused for filing  
399 or withdrawn, however, may renew its request for a small business waiver if the applicant  
400 resubmits the same application.

401  
402 If an applicant does not submit the application for which it was granted a small business waiver,  
403 the applicant may qualify again for a small business waiver.

404  
405

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<sup>28</sup> Section 736(d)(3)(B) of the FD&C Act.

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### 406 V. EXEMPTIONS AND REFUNDS

407

#### 408 A. Orphan Designated Products

409

##### 410 1. Application Fees

411

412 Under section 736(a)(1)(F) of the FD&C Act, a human drug application for a product that has  
413 been designated as a drug for a rare disease or condition (referred to as an orphan drug) under  
414 section 526 of the FD&C Act is not subject to an application fee unless the human drug  
415 application includes an indication for other than a rare disease or condition.

416

417 If an application qualifies for an orphan exemption, the applicant does not need to send FDA a  
418 written request. The applicant should simply notify FDA that it is claiming the orphan  
419 exemption when it completes and submits the User Fee Cover Sheet, Form FDA 3397.<sup>29</sup> The  
420 User Fee Cover Sheet should be included with the application, and a brief statement claiming the  
421 orphan exception should be included in the cover letter. ***If the applicant paid the application fee  
422 in advance of receiving the orphan drug designation, the applicant must submit a written  
423 request for a refund no later than 180 calendar days after such fee is due.***<sup>30</sup> For an applicant  
424 who paid the application fee in advance and has not yet received an orphan drug designation,  
425 FDA recommends that the applicant request a refund in the cover letter at the time the applicant  
426 submits the application, in anticipation of receiving orphan drug designation. If orphan  
427 designation is granted more than 180 calendar days after the application is submitted, the  
428 applicant will not be eligible for a refund at that time *unless* it submitted a refund request within  
429 180 calendar days of submitting the application. Section VI provides further information about  
430 refund requests.

431

##### 432 2. Program Fees

433

434 Under section 736(k) of the FD&C Act, a drug product designated under section 526 of the  
435 FD&C Act for a rare disease or condition and approved under section 505 of the FD&C Act or  
436 section 351 of the PHS Act is exempt from the program fee if it meets the public health  
437 requirements contained in the FD&C Act as such requirements are applied to requests for  
438 waivers of the program fee. In addition, the applicant must have less than \$50 million in gross  
439 worldwide revenue during the year preceding the request for exemption.<sup>31</sup>

440

441 An applicant seeking to avail itself of this exemption should submit a certification that its gross  
442 worldwide revenues, including affiliates, did not exceed \$50 million for the 12 months before the  
443 request.<sup>32</sup> The applicant should also submit financial documentation that supports the  
444 certification, such as financial statements that show intangible assets, other income, net gain on  
445 financial assets, foreign exchange gains, and interest income.

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<sup>29</sup> For more information about completion and submission of the User Fee Cover Sheets, see <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm>.

<sup>30</sup> Section 736(i) of the FD&C Act.

<sup>31</sup> Section 736(k)(1)(B) of the FD&C Act.

<sup>32</sup> Section 736(k)(2) of the FD&C Act.

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446  
447 Upon review of an applicant’s certification and accompanying information, FDA may contact  
448 the applicant to request further information, if needed, and for clarification of the information  
449 asserted in the applicant’s certification. FDA may request information about the applicant and  
450 its affiliates, such as financial statements, annual reports, and documents identifying affiliate  
451 relationships. If such information is not provided, FDA may not be able to verify an applicant’s  
452 certification and therefore may deny the orphan drug exemption request. Section VI provides  
453 information about how to submit a request for an exemption or refund of the program fee.  
454

### **B. State or Federal Government Entity**

456  
457 An application submitted by a State or Federal government entity for a drug that is *not*  
458 *distributed commercially* is not considered a “human drug application” under section 735(1) of  
459 the FD&C Act. If the application is not considered a human drug application, then application  
460 fees are not assessed and the program fee does not apply.  
461

462 For the purposes of the State and Federal exemption from user fees under the FD&C Act, FDA  
463 interprets *distributed commercially* means any distribution in exchange for financial  
464 reimbursement, goods, or services, whether or not the amount of the charge covers the full costs  
465 associated with the product. Under FDA’s interpretations, any recovery by the applicant of all or  
466 part of the costs of manufacture or distribution of a product would make the distribution  
467 commercial.  
468

### **C. No Substantial Work**

470  
471 Under section 736(a)(1)(G) of the FD&C Act, if an application is withdrawn after the application  
472 is filed, FDA may refund the fee or a portion of the fee if no substantial work was performed on  
473 the application after the application was filed. FDA has sole discretion in determining whether  
474 any portion of the fee may be refunded. A determination concerning a refund under this section  
475 is not reviewable.<sup>33</sup>  
476

## **VI. SUBMITTING REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS**

### **A. Timing of Requests**

#### *1. Deadline to Request a Waiver, Reduction, or Refund*

483  
484 Under section 736(i) of the FD&C Act, to qualify for a waiver or reduction in user fees as well as  
485 a refund for a fee paid, an applicant must submit to FDA a written request for a user fee waiver,  
486 reduction or refund no later than 180 calendar days after the fee is due.  
487

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<sup>33</sup> Section 736(a)(1)(G) of the FD&C Act.



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488 For example, if an applicant receives a program fee invoice from FDA, FDA expects the invoice  
489 to be paid by the due date. The applicant can then submit a written request for a waiver,  
490 reduction, or refund of the fee(s) within 180 calendar days from the date when the invoice is due.  
491 If the request is submitted within 180 calendar days of the due date (i.e., if the request is timely),  
492 FDA will evaluate the applicant's request. If FDA determines that the applicant qualifies for a  
493 waiver, reduction, or refund, the Agency will grant the applicant's request.

494  
495 To avoid having to pay a fee, an applicant can submit a request for a waiver or reduction in  
496 advance of when the program fee invoice is due to be paid, or in advance of submitting an  
497 application (see sections VI.A.3 and 4 below).

498  
499 If the applicant submits a waiver or exemption request and pays the relevant fee before receiving  
500 a determination from FDA on the waiver or exemption, the applicant should submit a refund  
501 request not later than 180 calendar days after such fee is due in order to qualify for a refund.

502  
503 *2. Consequences for Failure to Pay User Fees Due to Waiver or Reduction Delays*

504  
505 A human drug application or supplement submitted by a person subject to fees under section  
506 736(a) of the FD&C Act is considered incomplete and will not be accepted for filing until all  
507 such fees owed by the person have been paid. For example, if a person submits an application  
508 without an application fee or if the person is in arrears for nonpayment of any prescription drug  
509 program fees, the application will be incomplete and FDA will not accept it for filing. Note that  
510 the term person as used here includes an affiliate of the person, which means that an affiliate's  
511 failure to pay all of the user fees that it owes will affect the applicant's ability to file an  
512 application.

513  
514 *3. Recommended Time Frame to Submit a Request for a Waiver or Reduction of the*  
515 *Application Fee*

516  
517 FDA encourages applicants to submit a request for a waiver or reduction in an application fee  
518 approximately 3-4 months before submission of the application. Under normal circumstances  
519 and depending on available resources, FDA will try to make its determination on the waiver  
520 request before the application is submitted upon which the fee is due.

521  
522 FDA discourages applicants from submitting application fee waiver or reduction requests more  
523 than 4 months before the submission of an application because the circumstances that support an  
524 applicant's request are subject to change. FDA considers it unreasonable to assume that those  
525 circumstances will continue to exist for longer than 4 months before the submission of an  
526 application.

527  
528 *4. Recommended Time Frame to Submit a Request for a Waiver or Reduction of the*  
529 *Program Fee*

530  
531 The time frame to submit a request for a waiver or reduction of the program fee is the same as  
532 for an advance request for an application fee waiver or reduction: an applicant seeking a waiver

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533 or reduction of the program fee should generally submit a request for a waiver or reduction 3 to 4  
534 months before the fee is due. Annual program fees are due on October 1, or the first business  
535 day after the enactment of the appropriations act providing for the collection and obligation of  
536 PDUFA fees for that fiscal year, whichever occurs later.<sup>34</sup> Thus, an applicant that wishes to  
537 obtain a waiver or reduction in advance should submit its request between June 1 and July 1.  
538 Under normal circumstances and depending on available resources, FDA will try to complete its  
539 evaluation of the request before the due date of the program fee.

540  
541 The FD&C Act does not provide for deferral of user fees, and FDA does not grant deferrals of  
542 user fees based on pending waiver or reduction requests. FDA therefore expects that all program  
543 fees will be paid without regard to a pending request for a fee waiver or reduction. This  
544 approach ensures that the steady funding stream Congress intended will be achieved, and should  
545 deter the filing of frivolous waiver or reduction requests.

546  
547 Ordinarily, FDA expects to grant a reduction or waiver of a program fee only for the current  
548 year. If an applicant wishes to have a program fee waived or reduced for assessments in future  
549 years, it should make a new request for a waiver or reduction each year.

### **B. Content and Format of Requests, Excluding Small Business Waiver Requests**

#### *1. General Information*

555 Requests for CDER and CBER user fee waivers, reductions, and refunds will be reviewed and  
556 granted or denied by the Division of User Fee Management and Budget Formulation within  
557 CDER. However, reduction and refund requests for biological products regulated by CBER will  
558 be reviewed and granted or denied by CBER's Center Director.

559  
560 FDA recommends that each waiver or reduction request be submitted in writing and that it  
561 contain the following information:

- 562  
563 • Name of applicant requesting the waiver, including company name, address, contact,  
564 telephone number, and e-mail address
- 565  
566 • If an agent is submitting the request on behalf of an applicant, authorization from the  
567 applicant for the agent to act on the applicant's behalf
- 568  
569 • Application number, i.e. NDA, BLA, or IND
- 570  
571 • Trade and established names of product(s) covered by the waiver request
- 572  
573 • Identification of the specific fee(s) for which the waiver, refund, or reduction is requested
- 574

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<sup>34</sup> Section 736(a)(2)(A) of the FD&C Act.

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- 575 • Date on which the user fee payment was made or will be made for which a waiver or  
576 reduction is requested  
577
- 578 • Statutory provision under which a waiver or reduction is requested  
579
- 580 • Information and analyses demonstrating eligibility for the waiver or reduction  
581
- 582 • Rationale for why the waiver, reduction or refund request should be granted  
583
- 584 • A list of the applicant's affiliates<sup>35</sup>  
585
- 586 • For public health and barrier to innovation waivers, a current annual financial report for  
587 the applicant and the applicant's affiliates. If a current annual financial report is not  
588 available, a report that includes total cash and cash equivalents, accounts receivables,  
589 inventories, short and long-term investment marketable securities, deferred revenue,  
590 prepaid expenses and any other net proceeds received during the fiscal year that will  
591 increase the applicant's and its affiliates' cash flow even if not recorded under current  
592 assets  
593
- 594 • For requests for an orphan drug exemption to the program fee, a certification that its  
595 gross worldwide revenues, including affiliates, did not exceed \$50 million for the 12  
596 months before the request and financial documentation that supports the certification,  
597 such as financial statements that show intangible assets, other income, net gain on  
598 financial assets, foreign exchange gains, interest income, and net proceeds  
599

### *2. Additional Specific Information for Application Fee Waiver or Reduction Requests*

602 In addition to the general information specified above, requests for waivers or reductions in  
603 **application fees** should include the following:

- 604 • Date the application was or is intended to be submitted  
605
- 606 • Whether clinical data are expected to be required for approval  
607

### *3. Additional Specific Information Requested for Program Fee Waiver or Reduction Requests*

612 In addition to the general information specified above, requests for waivers or reductions in the  
613 **program fee** should include the following:  
614

---

<sup>35</sup> 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. 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.

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- 615 • Name of the application holder, if different from the name of the applicant requesting the  
616 waiver
- 617
- 618 • Specific strength, dosage form, and route of administration
- 619
- 620 • Invoice date and number (or copy of the invoice)
- 621

### **C. Content and Format of Request for a Small Business Waiver**

622 To qualify for a small business waiver of the application fee, an entity must submit to FDA a  
623 written request for such a waiver and a certification that the entity meets the requirements for the  
624 waiver. Applicants should submit requests for a small business waiver of the application fee and  
625 refund due to the small business waiver via Form FDA 3971, attached as Appendix 1. The  
626 completed form should be submitted via email to [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov) with the  
627 subject line, Small Business Waiver Request – [Applicant Name].  
628

629 Upon receipt of Form FDA 3971, FDA may contact the applicant to request additional  
630 information and clarification of the information supporting the assertions in Form FDA 3971.  
631 Examples of information that may be requested include, but are not limited to the following:  
632

- 633 • A copy of the applicant’s Articles of Incorporation and Bylaws;
- 634
- 635 • The applicant’s last annual statement to shareholders; and
- 636
- 637 • A breakdown of the number of persons employed full time, part time, temporarily, or  
638 otherwise by the applicant and affiliates during each of the pay periods for the 12 months  
639 preceding the company’s certification.  
640

641 Occasionally, FDA finds entities to be affiliated with the applicant that the applicant did not  
642 identify as one of its affiliates in its initial waiver or exemption submission. When determining  
643 whether parties are affiliated for purposes of user fee assessment under PDUFA, the critical  
644 factor is whether one party controls or has the power to control another entity, or if a third party  
645 has the power to control both entities.<sup>36</sup> In such cases, FDA recommends that the applicant  
646 submit copies of any agreements between an applicant and the other entities that demonstrate the  
647 nature of the relationship the applicant has with the entity. If the requested supporting  
648 documentation is not submitted, FDA may deny the small business waiver request because there  
649 is insufficient evidence that the applicant meets the requirements in section 736(d)(1)(C) of the  
650 FD&C Act.  
651

652 Once FDA has identified and confirmed which entities are properly considered affiliates of the  
653 applicant and determined whether the applicant qualifies as a small business, it will evaluate  
654 whether the applicant is eligible for the small business waiver. Specifically, FDA determines  
655 whether the applicant or any of its affiliates has previously submitted a human drug application,  
656  
657

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<sup>36</sup> See section 735(11) of the FD&C Act.

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658 and whether the applicant has a drug product that has been approved under a human drug  
659 application and introduced or delivered for introduction into interstate commerce. After FDA  
660 assesses the applicant's eligibility for a small business waiver FDA will notify the applicant  
661 whether the waiver is granted.  
662

### **D. Refund Requests**

663  
664 To qualify for an application or program fee refund, an applicant must submit to FDA a written  
665 request for a refund not later than 180 calendar days from the date the fee is due.<sup>37</sup> Applicants  
666 may submit their written request for an application fee refund in the submission cover letter of  
667 their application. A copy of the cover letter or program fee refund request (for both CBER and  
668 CDER products) should be submitted via email to [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov).  
669

670  
671 Alternatively, an applicant may mail the request to FDA via the carrier of its choice. For the  
672 most updated mailing address, visit the following FDA website:  
673 <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>.  
674

## **VII. FDA RESPONSES TO REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS**

675  
676 FDA will review waiver, refund and reduction requests, consulting with relevant Agency  
677 officials as appropriate. If needed to support applicants' assertions that the applicant qualifies,  
678 FDA may request additional information and documentation from the applicant during its review  
679 of a waiver, reduction, or refund request. Failure to provide the requested information or  
680 documentation may result in a denial of a waiver, reduction, or refund. The Agency will respond  
681 to all such requests in a timely fashion based on available resources and collection time for  
682 additional information.  
683  
684  
685

## **VIII. APPEALS PROCESS**

### **A. Reconsideration Request**

686  
687  
688 If FDA fully or partially denies a request for a waiver, refund, or reduction of user fees, the  
689 applicant may request reconsideration of that decision. A request for reconsideration should be  
690 made within 30 calendar days of the issuance of FDA's decision to fully or partially deny a  
691 request for a waiver, refund, or reduction of user fees.  
692

693  
694 FDA recommends that requests for reconsideration state the applicant's reasons for believing  
695 that the decision is in error and include any additional information, including updated financial  
696 information that is relevant to the applicant's position. The Agency will issue a response upon  
697 reconsideration, setting forth the basis for the decision.  
698  
699  
700

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<sup>37</sup> Section 736(i) of the FD&C Act.

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701  
702 All requests for reconsideration (for both CBER and CDER regulated products) should be  
703 submitted via email to [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov) and should be addressed to the Division  
704 of User Fee Management and Budget Formulation, Attention: Division Director, Center for Drug  
705 Evaluation and Research.

706  
707 Alternatively, an applicant may mail the request to FDA via the carrier of its choice. For the  
708 most updated mailing address, visit the following FDA website:  
709 <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>.

### **B. Appeal Request**

710  
711  
712  
713 If a request is denied upon reconsideration, the applicant may choose to appeal the denial. A  
714 request for an appeal should be made within 30 calendar days of the issuance of FDA's decision  
715 to affirm its denial of a request for a waiver, refund, or reduction of user fees. The following  
716 information should be included in the appeal:

- 717
- 718 • The original waiver request
  - 719
  - 720 • The denial of the original waiver request
  - 721
  - 722 • The reconsideration request
  - 723
  - 724 • The denial of the reconsideration request
  - 725
  - 726 • A statement of the applicant's belief that the prior conclusions were in error.
  - 727

728 **No new information or new analyses should be presented in the appeal request.** If new  
729 information and/or analyses are presented in the appeal request, the appeal will not be accepted  
730 and the matter will be referred back to the original deciding official to consider the new  
731 information or analyses.

732  
733 All requests for appeals (for both CBER and CDER products) should be submitted to the  
734 Director of CDER's Office of Management via [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov) and a copy  
735 should be submitted to the CDER Formal Dispute Resolution Project Manager. The contact  
736 information can be found on the CDER Formal Dispute Resolution Web page.<sup>38</sup> Alternatively,  
737 an applicant can mail the request to FDA via the carrier of its choice. For the most updated  
738 mailing address, visit the following FDA website:  
739 <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>.

740 After FDA reviews the information submitted in the appeal request, for CDER regulated  
741 products, the Director of CDER's Office of Management will issue a written decision on the

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<sup>38</sup> See

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

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742 applicant's request; for CBER regulated products, the Director of CBER will issue a written  
743 decision on the applicant's request.

744

745 CDER Products

746

747 If the applicant's appeal is denied at one management level, the applicant can appeal the same  
748 matter to the next higher management level in the Center chain of command. A new request  
749 should be submitted for each appeal to the next management level and should follow the process  
750 provided in this guidance. If the applicant has exhausted the Center's management levels and  
751 remains unsatisfied with the decision, the applicant may request review of the matter by the  
752 Commissioner under 21 CFR 10.75(c). Requests for review by the Commissioner should be  
753 submitted to FDA's Ombudsman, with copies provided to the Center that denied the appeal.  
754 Review of such matters by the Commissioner is discretionary.<sup>39</sup>

755

756 CBER Products

757

758 If the applicant's appeal is denied by the Director of CBER, the applicant may request review of  
759 the matter by the Commissioner of Food and Drugs (Commissioner) under 21 CFR 10.75(c).  
760 Requests for review by the Commissioner should be submitted to the FDA's Ombudsman, with  
761 copies provided to the Center that denied the appeal. Review of such matters by the  
762 Commissioner is discretionary.

763

764

### **IX. DISCLOSURE OF PUBLIC INFORMATION**

766

767 FDA may disclose information publicly about its actions granting or denying waivers, refunds  
768 and reductions. This disclosure will be consistent with the laws and regulations governing the  
769 disclosure of confidential commercial or financial information.

770

771

### **X. PAPERWORK REDUCTION ACT OF 1995**

773

774 This guidance contains information collection provisions that are subject to review and approval  
775 by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995  
776 (44 U.S.C. 3501-3520). "Collection of information" is defined in 44 U.S.C. 3502(3) and 5  
777 C.F.R. 1320.3(c) and includes Agency requests or requirements that members of the public  
778 submit reports, keep records, or provide information to a third party. The guidance refers to the  
779 following forms: (1) Form FDA 3397 and (2) Form FDA 3971.

780

781 The information collections of this draft guidance have been submitted for OMB renewal of  
782 approval under OMB control number 0910-0693.

783

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<sup>39</sup> See 40 FR 40682, 40693 (Sep. 3, 1975).

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784 Collection of information for completing and submitting Form FDA 3397 (Prescription Drug  
785 User Fee Cover Sheet) is previously approved under OMB control number 0910-0297.  
786 Collections of information associated with the submission of a new drug application or biologics  
787 license application are approved under OMB control numbers 0910-0001 and 0910-0338,  
788 respectively.  
789

790 The time required to complete the information collections included in this guidance are estimated  
791 to average 16 hours for a request for a waiver, reduction, refund, or exemption of certain user  
792 fees; 24 hours per response for a reconsideration of a request; and 12 hours for an appeal of a  
793 waiver, reduction, or refund decision. These estimates include the time to review instructions,  
794 gather the data needed, and complete and review the information collection.  
795

796 Form FDA 3971 is the collection of information submitted when requesting the small business  
797 waiver. Use of form FDA 3971 does not change the burden previously approved under OMB  
798 control number 0910-0693 for submitting or evaluating small business waivers. It facilitates the  
799 presentation of the information required for evaluation of the small business waiver with the use  
800 of a standardized form and an electronic fillable format.  
801

802 Send any comments regarding the burden estimate or suggestions for reducing this burden to the  
803 following:  
804

805 Department of Health and Human Services  
806 Food and Drug Administration  
807 Office of Operations  
808 Paperwork Reduction Act (PRA) Staff  
809 PRAStaff@fda.hhs.gov  
810



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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Prescription Drug and Biosimilar User Fee Acts**  
**Small Business Waiver and Refund Request**

Form Approved: OMB No. 0910-0693  
Expiration Date: October 31, 2020  
See PRA Statement on last page.

**Section I: Applicant Information**

1. Applicant Name

Former Names (if applicable)

2. Telephone Number (Including area and country codes)

3. Fax Number (Including area and country codes)

4. Address (No P.O. boxes allowed)

5. Federal Tax ID Number (Required for all U.S. applicants)

Address 1 (Street address)

6. DUNS Number

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

7. Number of Employees

City

State/Province/Region

Country

ZIP or Postal Code

8. User Fee Program for which the action is requested (Select one)

PDUFA

BsUFA

9. Human Drug/Biosimilar Biological Product Applications (Applicant)

Product Name

Application Number

Submission Date

Application Status (Select from drop-down list)

Is this the first application the Applicant has submitted to the FDA for review?

Yes

No

10. Human Drug/Biosimilar Biological Products (Applicant)

Does the Applicant have drug products approved under a human drug or biosimilar biological product application by the FDA that have been introduced or delivered for introduction into interstate commerce?

Yes

No

11. Small Business Waiver (Applicant)

Has the Applicant previously received a Small Business Waiver for a human drug or biosimilar biological product? (See instructions for details.)

Yes

No

**Section II: Affiliate Information (Enter information for each entity affiliated with the Applicant)**

Provide information for each of the Applicant's domestic and foreign affiliates. For multiple affiliates, click the "Add Affiliate" button for each additional entry. Refer to Instructions, Section II for additional information.

The Applicant does NOT have any Affiliates (Check if applicable):

12. Affiliate Name

<b>13. Affiliate Address (No P.O. boxes allowed)</b>		14. DUNS Number
Address 1 (Street address)		15. Number of Employees
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City	State/Province/Region	
Country	ZIP or Postal Code	

16. Name of Affiliate's Point of Contact	17. E-mail Address	18. Telephone Number
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<b>19. Small Business Waiver (Affiliate)</b>	
Has the Affiliate previously received a Small Business Waiver for a human drug or biosimilar biological product application? (See instructions for details.)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>20. Human Drug/Biosimilar Biological Product Applications (Affiliate)</b>	
Has the Affiliate ever submitted a human drug or biosimilar biological product application?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	

Click for an additional set of Section II affiliate entries (includes items 12 through 20). May be repeated.

[Add Affiliate](#)

**Section III: Refund**

21. Did the Applicant pay a fee for this application for \_\_\_\_\_ prior to requesting this Small Business Waiver? *Product Name*

Yes       No

NDA or BLA Number	Payment Amount	PIN/Invoice Number	Payment Reference Number	Refund Amount Requested

**Section IV: Certification**

Review, sign, and date the following certification statement:

**I CERTIFY THAT** \_\_\_\_\_  
*Applicant Name (must be identical to item 1)*

**BSUFA:**

- i Has fewer than 500 employees, including employees of Affiliates;
- ii. Does not have a drug product that has been approved under a human drug application or biosimilar biological product application by the FDA and introduced or delivered for introduction into interstate commerce;
- iii. Requests a Small Business Waiver for the first biosimilar biological product application that the Applicant or its Affiliate has submitted.

**PDUFA:**

- i Has fewer than 500 employees, including employees of Affiliates;
- ii. Does not have a drug product that has been approved under a human drug application by the FDA and introduced or delivered for introduction into interstate commerce;
- iii. Requests a Small Business Waiver for the first human drug application that the Applicant or its Affiliate has submitted.

I further certify that, to the best of my knowledge, the information I have provided in this form is complete, accurate and has been verified. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

22. Name of Applicant's Responsible Official		23. Title	
24. Telephone Number		25. Email Address	
26. Responsible Official's Address			
Address 1 (Street address)			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City		State/Province/Region	
Country		ZIP or Postal Code	
27. Signature			28. Date (mm/dd/yyyy)
<p>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 <a href="#">here</a>.</p>			

**Send Completed Form FDA 3971 to FDA via**

**Email (preferred):** [CDERCollections@FDA.HHS.GOV](mailto:CDERCollections@FDA.HHS.GOV) **or** **Physical Mail:** Division of User Fee Management and Budget Formulation  
Food and Drug  
Administration 10001 New  
Hampshire Ave. Silver  
Spring, MD 20993-0002

**FDA Use Only**

Date Received: \_\_\_\_\_  **Approved**  **Denied**

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*Contains Nonbinding Recommendations*

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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 40 minutes 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.”*