

1 **SEC. 101. SHORT TITLE; REFERENCES IN ACT; FINDINGS.**

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3 (a) **Short Title.**—This Act may be cited as the “Generic Drug User Fee
4 Amendments of 2012”.

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6 (b) **References in Act.**—Except as otherwise specified, amendments made by this
7 Act to a section or other provision of law are amendments to such section or other
8 provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).
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10 (c) **Findings.**—The Congress finds that the fees authorized by the amendments made in
11 this Act will be dedicated, as set forth in the goals identified in the letters from the
12 Secretary of Health and Human Services to the Chairman of the Committee on Health,
13 Education, Labor, and Pensions of the Senate and the Chairman of the Committee on
14 Energy and Commerce of the House of Representatives, as set forth in the Congressional
15 Record. These fees are intended to help the Food and Drug Administration (FDA) ensure
16 that participants in the United States generic drug system comply with United States
17 quality standards, and to increase the likelihood that American consumers get timely
18 access to low cost, high quality generic drugs. A comprehensive human generic drug user
19 fee program, to be supplemental to traditional appropriated funding, should be focused on
20 three key aims:

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22 Safety – Ensure that industry participants, foreign or domestic, who participate in the
23 United States generic drug system are held to consistent high quality standards and are
24 inspected biennially, using a risk-based approach, with foreign and domestic parity.
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26 Access – Expedite the availability of low cost, high quality generic drugs by bringing
27 greater predictability to the review times for abbreviated new drug applications,
28 amendments and supplements, increasing predictability and timeliness in the review
29 process.
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31 Transparency – Enhance FDA’s ability to protect Americans in the complex global
32 supply environment by requiring the identification of facilities involved in the
33 manufacture of generic drugs and associated active pharmaceutical ingredients, and
34 improving FDA’s communications and feedback with industry in order to expedite
35 product access.
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37
38 **SEC. 102. Authority to assess and use human generic drug fees**

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40 Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et.
41 seq) is amended by inserting after part 7 the following:

42
43 **"PART 8 – FEES RELATING TO GENERIC DRUGS**

44
45 **"SEC. 744G. Authority to assess and use human generic drug fees.**

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(a) **Types of fees** - Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) **One Time Backlog Fee for Abbreviated New Drug Applications Pending on October 1, 2012.**

(A) **In general** -- Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as established under subparagraph (B).

(B) **Method of Fee Amount Calculation; Notice** -- The amount of each one time backlog fee shall be calculated by dividing \$50 million by the total number of applicable abbreviated new drug applications pending on October 1, 2012 that have not received a tentative approval as of that date. By October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the fee.

(C) **Fee Due Date** -- The fee required by subparagraph (A) shall be paid no later than 30 calendar days from the publication of the notice specified in subparagraph (B).

(2) **Drug Master File Fee.**

(A) **In general** -- Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012 in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee established under subsection (d). Once a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is referenced in additional generic drug submissions.

(B) **Method of Fee Amount Calculation; Notice** -- The amount of the drug master file fee established in subparagraph (A) shall be calculated pursuant to subsection (d). For fiscal year 2013, by October 31, 2012, the Secretary shall cause to be published in the Federal Register a notice announcing the amount of the drug master file fee. For each of fiscal years 2014 to 2017, the Secretary shall cause to be published in the Federal Register, 60 days before the start of each such fiscal year, the amount for the drug master file fee established by this paragraph for the coming fiscal year.

(C) **Availability for Reference** -- Starting 20 calendar days after the date that payment of fees for the Type II active pharmaceutical ingredient drug master file is first required as provided in subparagraph (D), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary. To be deemed available for reference:

- 90 (i) the person that owns a Type II active pharmaceutical ingredient
91 drug master file must pay the fee required under subparagraph (A)
92 as calculated under subsection (d); and
93 (ii) the drug master file must not have failed an initial completeness
94 assessment by the Secretary, in accordance with criteria to be
95 published by the Secretary.

96 The Secretary shall make available a list of the drug master file numbers
97 that correspond to drug master files that have successfully undergone an
98 initial completeness assessment and are available for reference.

99 (D) **Fee Due Date –**

100 (i) Starting 30 calendar days after publication of the notice
101 provided for in subparagraph (B), or the date that is 30 calendar days after
102 the date an appropriations Act provides for the collection and obligation of
103 fees under this section, whichever is later, a drug master file fee shall be
104 paid no later than upon submission of the first generic drug submission
105 submitted on or after October 1, 2012, that references the associated Type
106 II active pharmaceutical ingredient drug master file, subject to clause (ii).

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108 (ii) If an appropriations Act providing for the collection and
109 obligation of fees under this section is not enacted by October 1, 2012, the
110 fee shall be due on the later of submission of---

111 (I) the first generic drug submission submitted after
112 October 1, 2012, that references the associated Type II active
113 pharmaceutical ingredient drug master file; or

114 (II) 30 calendar days after the date that such an
115 appropriations Act is enacted.

116 (iii)(I) If an abbreviated new drug application or supplement to an
117 abbreviated new drug application submitted on or after October 1, 2012
118 references a Type II active pharmaceutical ingredient drug master file for
119 which a fee under subparagraph (A) is due that has not been paid, the
120 Secretary shall notify the sponsor of the abbreviated new drug application
121 or supplement of the failure of the owner of the Type II active
122 pharmaceutical ingredient drug master file to pay the applicable fee.

123 (II) If such fee is not paid within 20 calendar days of the
124 Secretary providing the notification, the abbreviated new drug application
125 or supplement to an abbreviated new drug application shall not be
126 received, within the meaning of 505(j)(5)(A) as implemented in Food and
127 Drug Administration regulations.
128

129 (3) **Abbreviated New Drug Application and Prior Approval Supplement Filing**
130 **Fee**

131 (A) **In general –** Each applicant that submits, on or after October 1, 2012, an
132 abbreviated new drug application or a prior approval supplement to an
133 abbreviated new drug application shall be subject to a fee for each such
134 submission as follows:

- 135 (i) A fee established under subsection (d) for an abbreviated new drug
136 application.
- 137 (ii) A fee established under subsection (d) for a prior approval
138 supplement to an abbreviated new drug application.
- 139 (B) **Method of Fee Amount Calculation; Notice** – The amount of the
140 abbreviated new drug application filing fee and the prior approval
141 supplement filing fee established in subparagraph (A) shall be calculated
142 pursuant to subsection (d). For fiscal year 2013, the Secretary shall cause
143 to be published in the Federal Register a notice announcing the amount of
144 the fees provided for in subparagraph (A) by October 31, 2012. For each
145 of fiscal years 2014 through 2017, the Secretary shall cause to be
146 published in the Federal Register, 60 days before the start of each such
147 fiscal year, the amount of the fees established by this paragraph for the
148 coming fiscal year.
- 149 (C) **Fee Due Date** – The fees required by subparagraphs (A) and (F) shall be
150 due no later than the date of submission of the abbreviated new drug
151 application or prior approval supplement, except that, for fiscal year 2013,
152 the fee shall be due on the later of---
- 153 (i) the date of submission of the abbreviated new drug application
154 or prior approval supplement; or
- 155 (ii) 30 calendar days after publication of the notice referred to in
156 subparagraph (B), if an appropriations Act is not enacted providing for the
157 collection and obligation of fees under this section by the date of
158 submission of the application or prior approval supplement.
- 159 (D) **Refund of fee if abbreviated new drug application is not considered to**
160 **have been received** -- The Secretary shall refund 75 percent of the fee
161 paid under subparagraph (C) for any abbreviated new drug application or
162 prior approval supplement to an abbreviated new drug application that the
163 Secretary considers not to have been received pursuant to section
164 505(j)(5)(A) as implemented in Food and Drug Administration
165 regulations, for a cause other than failure to pay fees.
- 166 (E) **Fee for an application the Secretary considers not to have been**
167 **received, or that has been withdrawn** -- An abbreviated new drug
168 application or prior approval supplement that was submitted on or after
169 October 1, 2012 and that the Secretary considers not to have been
170 received, or that has been withdrawn, shall be subject to a new full fee
171 under subparagraph (A) upon resubmission of the application or a
172 subsequent new submission following the applicant's withdrawal of the
173 application.
- 174 (F) **Fee for Active Pharmaceutical Ingredient Information Not Included**
175 **by Reference to Type II Active Pharmaceutical Ingredient Drug**
176 **Master File.--**
- 177 (i) An applicant that submits a generic drug submission on or after
178 October 1, 2012, shall pay a fee, as determined in clause (ii), in addition to
179 the application fee required by subparagraph (A), if—

180 (I) such submission contains information concerning the
181 manufacture of an active pharmaceutical ingredient at a facility by
182 means other than reference by a letter of authorization to a Type II
183 active pharmaceutical drug master file; and

184 (II) a fee in the amount equal to the drug master file fee
185 established in paragraph (2) has not been previously paid with
186 respect to such information.

187 (ii) The fee referred to in clause (i) shall be determined by—

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189 (I) totaling the number of such active pharmaceutical
190 ingredients;

191 (II) for each such ingredient that is manufactured at more
192 than one such facility, totaling the number of such additional
193 facilities;

194 (III) adding the totals determined in subclauses (I) and (II);
195 and

196 (IV) multiplying the number determined pursuant to
197 subclause (III) by the amount equal to the drug master file fee
198 established in paragraph (2).
199

200 (4) **Generic Drug Facility Fee and Active Pharmaceutical Ingredient Facility Fee**

201 (A) **In general** – Facilities identified, or intended to be identified, in at least
202 one generic drug submission that is pending or approved to produce a
203 finished dosage form of a human generic drug or an active pharmaceutical
204 ingredient contained in a human generic drug shall be subject to fees as
205 follows:

206 (i) **Generic drug facility** -- Each person that owns a facility which is
207 identified or intended to be identified in at least one generic drug
208 submission that is pending or approved to produce one or more
209 finished dosage forms shall be assessed an annual fee established
210 under subsection (d) for each such facility.

211 (ii) **Active pharmaceutical ingredient facility** -- Each person that
212 owns a facility which produces, or which is pending review to
213 produce, one or more active pharmaceutical ingredients identified,
214 or intended to be identified, in at least one generic drug submission
215 that is pending or approved or in a Type II active pharmaceutical
216 ingredient drug master file referenced in such a generic drug
217 submission, shall be assessed an annual fee established under
218 subsection (d) for each such facility.

219 (iii) **Facilities producing both active pharmaceutical ingredients**
220 **and finished dosage forms** -- Each person that owns a facility
221 identified, or intended to be identified, in at least one generic drug
222 submission that is pending or approved to produce both one or
223 more finished dosage form subject to clause (i) and one or more
224 active pharmaceutical ingredient subject to clause (ii) shall be
225 subject to fees under both such clauses for that facility.

226 (B) **Method of Fee Calculation; Notice**—The fees established by
227 subparagraph (A) shall be calculated as specified in subsection (d).
228 For fiscal year 2013, the Secretary shall cause to be published in the
229 Federal Register a notice announcing the amount of the fees provided for
230 in subparagraph (A) within the timeframe specified in subsection (d). For
231 each of fiscal years 2014 through 2017, the Secretary shall cause to be
232 published in the Federal Register, with 60 days before the start of each
233 such fiscal year, the amount of the fees provided for in subparagraph (A)
234 within the timeframe specified in subsection (d) for the coming fiscal year.

235 (C) **Fee Due Date**—
236 (i) For fiscal year 2013, the fees required by subparagraph (A)
237 shall be paid within 45 calendar days of the publication of the notice
238 required in subparagraph (B) except that if an appropriations Act is not
239 enacted providing for the collection and obligation of fees under this
240 section by the date of the notice required by subparagraph (B), the fee
241 shall be due 30 calendar days after the date that such an appropriations Act
242 is enacted.

243 (ii) For each of fiscal years 2014 through 2017, such fees shall be
244 due on the later of—

245 (I) the first business day after October 1 of each such year;
246 or

247 (II) the first business day after the enactment of an
248 appropriations Act providing for the collection and obligation of
249 fees for such year under this section.

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251 (iii) If an abbreviated new drug application or supplement to an
252 abbreviated new drug application submitted on or after October 1, 2012
253 references a facility for which a facility fee that is due has not been paid,
254 the Secretary shall notify the sponsor of the generic drug submission of the
255 failure of the owner of the facility to pay the facility fee, and if the facility
256 fee is not paid within 20 calendar days of the Secretary providing the
257 notification, the abbreviated new drug application or supplement to an
258 abbreviated new drug application shall not be received, within the
259 meaning of 505(j)(5)(A) as implemented in Food and Drug Administration
260 regulations.

261
262 (b) **Fee revenue amounts**

263 (1) **In general** – For fiscal year 2013, fees under subsection (a) shall be established to
264 generate a total estimated revenue amount under such subsection of \$299,000,000.
265 Of that amount, \$50,000,000 shall be generated by the one time backlog fee for
266 generic drug applications pending on October 1, 2012 established in subsection
267 (a)(1) of such subsection. For each of the fiscal years 2014 through 2017, fees
268 under paragraphs (2)-(4) of subsection (a) shall be established to generate a total
269 estimated revenue amount under such subsection that is equal to the sum of
270 \$299,000,000, as adjusted pursuant to subsection (c).

- 271 (2) **Types of fees** -- Of the total revenue amount determined for a fiscal year under
272 paragraph (1)—
273 (A) for fiscal year 2013, \$50 million shall be derived from fees under
274 subsection (a)(1) (relating to abbreviated new drug applications pending
275 on October 1, 2012); and \$249 million will be derived from fees divided
276 as follows:
277 (i) 6% shall be derived from fees under subsection (a)(2) (relating to
278 drug master files).
279 (ii) 24% shall be derived from fees under subsection (a)(3) (relating to
280 abbreviated new drug applications and supplements). The amount
281 of a fee for a prior approval supplement shall be half the amount of
282 the fee for an abbreviated new drug application.
283 (iii) 56 % shall be derived from fees under subsection (a)(4)(A)(i)
284 (relating to generic drug finished dosage form facilities). The
285 amount of the fee for a facility located outside the United States,
286 its territories and possessions shall be not less than \$15,000 and not
287 more than \$30,000 higher than the amount of the fee for a facility
288 located in the United States, its territories and possessions, as
289 determined by the Secretary on the basis of data concerning the
290 difference in cost between inspections of facilities located in the
291 United States, its territories and possessions, and those located
292 outside of the United States, its territories and possessions.
293 (iv) 14% shall be derived from fees under subsection (a)(4)(A)(ii)
294 (relating to active pharmaceutical ingredient facilities). The
295 amount of the fee for a facility located outside the United States,
296 its territories and possessions shall be not less than \$15,000 and not
297 more than \$30,000 higher than the amount of the fee for a facility
298 located in the United States, its territories and possessions, as
299 determined by the Secretary on the basis of data concerning the
300 difference in cost between inspections of facilities located in the
301 United States, its territories and possessions, and those located
302 outside of the United States, its territories and possessions.
303 (B) for fiscal years 2014 through 2017, \$299 million, as adjusted pursuant to
304 subsection (c), shall be derived from fees divided as follows:
305 (i) 6 % shall be derived from fees under subsection (a)(2) (relating to
306 drug master files).
307 (ii) 24 % shall be derived from fees under subsection (a)(3) (relating to
308 abbreviated new drug applications and supplements). The amount
309 of a fee for a prior approval supplement shall be half the amount of
310 the fee for an abbreviated new drug application.
311 (iii) 56 % shall be derived from fees under subsection (a)(4)(A)(i)
312 (relating to generic drug facilities). The amount of the fee for a
313 facility located outside the United States, its territories and
314 possessions shall be not less than \$15,000 and not more than
315 \$30,000 (based on current available data) higher than the amount
316 of the fee for a facility located in the United States, its territories

317 and possessions as determined by the Secretary on the basis of
318 data concerning the difference in cost between inspections of
319 facilities located in the United States, its territories and
320 possessions, and those located outside of the United States, its
321 territories and possessions.

- 322 (iv) 14 % shall be derived from fees under subsection (a)(4)(A)(ii)
323 (relating to active pharmaceutical ingredient facilities). The
324 amount of the fee for a facility located outside the United States,
325 its territories and possessions shall be not less than \$15,000 and not
326 more than \$30,000 (based on current available data) higher than
327 the amount of the fee for a facility located in the United States, its
328 territories and possessions as determined by the Secretary on the
329 basis of data concerning the difference in cost between inspections
330 of facilities located in the United States, its territories and
331 possessions, and those located outside of the United States, its
332 territories and possessions.

333
334 (c) **Adjustments**

- 335 (1) **Inflation adjustment** For fiscal year 2014 and subsequent fiscal years, the
336 revenues established in subsection (b) shall be adjusted by the Secretary by notice,
337 published in the Federal Register, for a fiscal year to reflect the sum of one plus —
338 (A) the average annual change in the cost, per full-time equivalent position of
339 the Food and Drug Administration, of all personnel compensation and
340 benefits paid with respect to such positions for the first 3 years of the
341 preceding 4 fiscal years multiplied by the proportion of personnel
342 compensation and benefits costs to total costs of human generic drug
343 activities for the first 3 years of the preceding 4 fiscal years, and
344 (B) the average annual change that occurred in the Consumer Price Index for
345 urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not
346 Seasonally Adjusted; All items; Annual Index) for the first 3 years of the
347 preceding 4 years of available data multiplied by the proportion of all
348 costs other than personnel compensation and benefits costs to total costs of
349 human generic drug activities for the first 3 years of the preceding 4 fiscal
350 years.

351 The adjustment made each fiscal year by this subsection will be added on a
352 compounded basis to the sum of all adjustments made each fiscal year after fiscal
353 year 2013 under this subsection.

- 354
355 (2) **Final year adjustment --** For fiscal year 2017, the Secretary may, in addition to
356 adjustments under paragraph (1), further increase the fee revenues and fees
357 established in subsection (b) if such an adjustment is necessary to provide for not
358 more than 3 months of operating reserves of carryover user fees for human generic
359 drug activities for the first 3 months of fiscal year 2018. Such fees may only be
360 used in fiscal year 2018. If such an adjustment is necessary, the rationale for the
361 amount of the increase shall be contained in the annual notice establishing fee
362 revenues and fees for fiscal year 2017. If the Secretary has carryover balances for

363 such process in excess of 3 months of such operating reserves, the adjustment
364 under this subparagraph shall not be made.
365

366 (d) **Annual fee setting**

367 (1) For fiscal year 2013 –

368 (A) The Secretary shall establish, by October 31, 2012 the one time generic
369 drug backlog fee for generic drug applications pending on October 1,
370 2012, the drug master file fee, the abbreviated new drug application fee,
371 and the prior approval supplement fee under subsection (a) , based on the
372 revenue amounts established under subsection (b).

373 (B) The Secretary shall establish, within 45 days after the date to comply with
374 the requirement for identification of facilities in subsection (f)(1), the
375 generic drug facility fee and active pharmaceutical ingredient facility fee
376 under subsection (a) based on the revenue amounts established under
377 subsection (b).

378 (2) For each of fiscal years 2014 through 2017, the Secretary shall, 60 days before the
379 start of each such fiscal year, establish the drug master file fee, the abbreviated
380 new drug application fee, the prior approval supplement fee, the generic drug
381 facility fee and the active pharmaceutical ingredient facility fee under subsection
382 (a), based on the revenue amounts established under subsection (b) and the
383 adjustments provided under subsection (c).
384

385 (e) **Limit**

386 The total amount of fees charged, as adjusted under subsection (c), for a fiscal year
387 may not exceed the total costs for such fiscal year for the resources allocated for
388 human generic drug activities.
389

390 (f) **Identification of facilities**

391 (1) By October 1, 2012, the Secretary shall cause to be published in the Federal
392 Register a notice requiring each person that owns a facility as identified in
393 subsection (a)(4)(A) or a site identified in subsection (f)(3) to identify each such
394 facility or site. Each such person shall comply with that requirement within 60
395 calendar days of the publication of such notice. For each subsequent fiscal year,
396 each such person shall submit, update, or reconfirm such information annually, on
397 or before June 1 of each year starting with June 1, 2013.
398

399 (2) The notice required by paragraph (1) shall specify the type of information to be
400 submitted and the means and format for submission of such information. At a
401 minimum the submission shall include for each such facility:

402 (A) identification of a facility identified or intended to be identified in an
403 approved or pending generic drug submission;

404 (B) whether the facility manufactures active pharmaceutical ingredients or
405 finished dosage forms, or both;

406 (C) whether or not the facility is located within the United States, its territories
407 and possessions;

- 408 (D) whether the facility manufactures positron emission tomography drugs
409 solely, or in addition to other drugs; and
410 (E) whether the facility manufactures drugs that are not generic drugs.
411

412 (3) Any person that owns or operates

- 413 (A) a site in which a bioanalytical study is conducted,
414 (B) a clinical research organization,
415 (C) a contract analytical testing site, or
416 (D) a contract repackager site

417 identified in a generic drug submission, shall provide to the Secretary information
418 concerning the ownership, name, and address of the site. The Secretary may, by
419 notice published in the Federal Register, specify the means and format for
420 submission of such information and may specify additional or different
421 information to be submitted. The Secretary's inspectional authority shall extend to
422 all such sites.
423

424 (g) **Effect of failure to pay fees**

- 425 (1) Failure to pay the fee established by subsection (a)(1) shall result in the Secretary
426 placing the person that owns the abbreviated new drug application subject to that
427 fee on an arrears list, such that no new abbreviated new drug applications or
428 supplement submitted on or after October 1, 2012 from that person, or any affiliate
429 of that person, will be received within the meaning of section 505(j)(5)(A) as
430 implemented in Food and Drug Administration regulations, until such outstanding
431 fee is paid.
432

- 433 (2) (A) Failure to pay the fee established by subsection (a)(2) within 20 calendar days
434 of the date due as specified in subparagraph (D) of such subsection will result in
435 the Type II active pharmaceutical ingredient drug master file not being deemed
436 available for reference.

437 (B) (i) Any generic drug submission submitted on or after October 1, 2012 that
438 references, by a letter of authorization, a Type II active pharmaceutical ingredient
439 drug master file that has not been deemed available for reference shall not be
440 received within the meaning of section 505(j)(5)(A) as implemented in Food and
441 Drug Administration regulations, unless the condition specified in clause (ii) is
442 met.

443 (ii) the condition specified in this clause is that the fee established under
444 subsection (a)(2) has been paid within 20 calendar days of the Secretary providing
445 the notification to the sponsor of the abbreviated new drug application or
446 supplement of the failure of the owner of the Type II active pharmaceutical
447 ingredient drug master file to pay the drug master file fee as specified in
448 subparagraph (D) of such subsection.
449

- 450 (3) Failure to pay the fee established by subsection (a)(3) within 20 calendar days of
451 the due date as specified in subparagraph (C) of such subsection will result in the
452 abbreviated new drug application or the prior approval supplement to an
453 abbreviated new drug application not being received within the meaning of section

454 505(j)(5)(A) as implemented in Food and Drug Administration regulations until
455 such outstanding fee is paid.

- 456
457 (4) Failure to pay the fee established by subsection (a)(4) within 20 calendar days of
458 the due date as specified in subparagraph (C) of such subsection will result in:
459 (A) identification of the facility on a publicly available arrears list, such that
460 no new abbreviated new drug applications or supplement submitted on or
461 after October 1, 2012 from that person, or any affiliate of that person, will
462 be received within the meaning of section 505(j)(5)(A) as implemented in
463 Food and Drug Administration regulations;
464 (B) any new generic drug submission submitted on or after October 1, 2012
465 that references such a facility shall not be received, within the meaning of
466 505(j)(5)(A) as implemented in Food and Drug Administration regulations
467 if the outstanding facility fee is not paid within 20 calendar days of the
468 Secretary providing the notification to the sponsor of the failure of the
469 owner of the facility to pay the facility fee as specified in subsection
470 (a)(4)(C); and
471 (C) all drugs or active pharmaceutical ingredients manufactured in such a
472 facility or containing an ingredient manufactured in such a facility being
473 deemed misbranded under section 502(aa).

474 The penalties in this paragraph shall apply until the fee established by
475 subsection (a)(4) is paid or the facility is removed from all generic drug
476 submissions that refer to the facility.
477

478 (h) **Limitations**

- 479 (1) **In general** -- Fees under subsection (a) shall be refunded for a fiscal year
480 beginning after fiscal year 2012 unless appropriations for salaries and expenses of
481 the Food and Drug Administration for such fiscal year (excluding the amount of
482 fees appropriated for such fiscal year) are equal to or greater than the amount of
483 appropriations for the salaries and expenses of the Food and Drug Administration
484 for the fiscal year 2009 (excluding the amount of fees appropriated for such fiscal
485 year) multiplied by the adjustment factor defined in subsection (m)(3) applicable
486 to the fiscal year involved.
487
488 (2) **Authority** -- If the Secretary does not assess fees under subsection (a) during any
489 portion of a fiscal year and if at a later date in such fiscal year the Secretary may
490 assess such fees, the Secretary may assess and collect such fees, without any
491 modification in the rate, for Type II active pharmaceutical ingredient drug master
492 files, abbreviated new drug applications and prior approval supplements, and
493 generic drug facilities and active pharmaceutical ingredient facilities at any time in
494 such fiscal year notwithstanding the provisions of subsection (a) relating to the
495 date fees are to be paid.

496
497 (i) **Crediting and availability of fees**
498

499 (1) **In general** -- Fees authorized under subsection (a) shall be collected and available
500 for obligation only to the extent and in the amount provided in advance in
501 appropriations Acts, subject to paragraph (2). Such fees are authorized to remain
502 available until expended. Such sums as may be necessary may be transferred from
503 the Food and Drug Administration salaries and expenses appropriation account
504 without fiscal year limitation to such appropriation account for salaries and
505 expenses with such fiscal year limitation. The sums transferred shall be available
506 solely for human generic drug activities.
507

508 (2) **Collections and appropriation acts**
509

510 (A) **In general.**—The fees authorized by this section—
511

512 i. shall be collected and available in each fiscal year in an amount not
513 to exceed the amount specified in appropriation Acts, or otherwise
514 made available for obligation for such fiscal year, subject to
515 subparagraphs (C) and (D); and
516

517 ii. shall be available for a fiscal year beginning after fiscal year 2012
518 to defray the costs of human generic drug activities (including such
519 costs for an additional number of full-time equivalent positions in
520 the Department of Health and Human Services to be engaged in
521 such activities), only if the Secretary allocates for such purpose an
522 amount for such fiscal year (excluding amounts from fees collected
523 under this section) no less than \$97 million multiplied by the
524 adjustment factor defined in subsection (m)(3) applicable to the
525 fiscal year involved.
526

527 (B) **Compliance.**--The Secretary shall be considered to have met the
528 requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by
529 appropriations and allocated for human generic activities are not more than 10
530 percent below the level specified in such subparagraph.
531

532 (C) **Fee collection during first program year.**—Until the date of enactment of
533 an Act making appropriations through September 30, 2013 for the salaries and
534 expenses account of the Food and Drug Administration, fees authorized by this
535 section for fiscal year 2013 may be collected and shall be credited to such account
536 and remain available until expended.
537

538 (D) **Provision for early payments in subsequent years.**—Payment of fees
539 authorized under this section for a fiscal year (after fiscal year 2013), prior to the
540 due date for such fees, may be accepted by the Secretary in accordance with
541 authority provided in advance in a prior year appropriations Act.
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544

- 545 (3) **Authorization of appropriations.** -- For each of the fiscal years 2013 through
546 2017, there is authorized to be appropriated for fees under this section an amount
547 equivalent to the total revenue amount determined under subsection (b) for the
548 fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph
549 (2) of this subsection.
550
- 551 (j) **Collection of unpaid fees** -- In any case where the Secretary does not receive payment of a
552 fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be
553 treated as a claim of the United States Government subject to subchapter II of chapter 37 of
554 title 31.
555
- 556 (k) **Construction** -- This section may not be construed to require that the number of full-time
557 equivalent positions in the Department of Health and Human Services, for officers,
558 employers, and advisory committees not engaged in human generic drug activities, be
559 reduced to offset the number of officers, employees, and advisory committees so engaged.
560
- 561 (l) **Positron Emission Tomography Drugs** -- Submission of an application for a positron
562 emission tomography drug or active pharmaceutical ingredient for a positron emission
563 tomography drug shall not require the payment of any fee under this section. Facilities that
564 solely produce positron emission tomography drugs shall not be required to pay a facility
565 fee as established in subsection (a)(4) . Facilities that produce positron emission
566 tomography drugs or active pharmaceutical ingredients of such drugs are required to be
567 identified pursuant to subsection (f). For purposes of this subsection, the term "positron
568 emission tomography drug" has the meaning given to the term "compounded positron
569 emission tomography drug" in section 201(ii), except that paragraph (1)(B) of such section
570 shall not apply.
571
- 572 (m) **Definitions** -- For purposes of this section,
573 (1) **Abbreviated new drug application** means an application submitted under
574 section 505(j), an abbreviated application submitted under section 507 (as in effect
575 on the day before the date of enactment of the Food and Drug Administration
576 Modernization Act of 1997 [enacted Nov. 21, 1997]), or an abbreviated new drug
577 application pursuant to regulations in effect prior to the implementation of the
578 Drug Price Competition and Patent Term Restoration Act of 1984 but does not
579 include an application for a positron emission tomography drug.
580
- 581 (2) **Active pharmaceutical ingredient** means
582 (A) a substance, or a mixture when the substance is unstable or cannot be
583 transported on its own, intended to be used as a component of a drug and
584 intended to furnish pharmacological activity or other direct effect in the
585 diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect
586 the structure or any function of the human body; or
587 (B) a substance intended for final crystallization, purification, or salt
588 formation, or any combination of those activities, to become the final
589 active pharmaceutical ingredient as defined in paragraph (A).
590

- 591 (3) **Adjustment factor** means a factor applicable to a fiscal year that is the
592 Consumer Price Index for all urban consumers (all items; United States city
593 average) for October of the preceding fiscal year divided by such Index for
594 October 2011.
595
- 596 (4) **Affiliate** means a business entity that has a relationship with a second
597 business entity if, directly or indirectly –
598 (A) one business entity controls, or has the power to control, the other
599 business entity; or
600 (B) a third party controls, or has power to control, both of the business
601 entities.
602
- 603 (5) **Facility** means business or other entity under one management either direct or
604 indirect and at one geographic location or address engaged in manufacturing or
605 processing an active pharmaceutical ingredient or a finished dosage form, but does
606 not include a business or other entity whose only manufacturing or processing
607 activities are one or more of the following: repackaging, relabeling, or testing. For
608 purposes of this definition, separate buildings within close proximity are
609 considered to be at one geographic location or address if the activities in them are
610 closely related to the same business enterprise, under the supervision of the same
611 local management, and are capable of being inspected by the Food and Drug
612 Administration during a single inspection.
613
- 614 (6) **Finished Dosage Form** means:
615 (A) a drug product in the form in which it will be administered to a patient,
616 such as a tablet, capsule, solution, or topical application ;
617 (B) a drug product in a form in which reconstitution is necessary prior to
618 administration to a patient, such as oral suspensions or lyophilized
619 powders; or
620 (C) any combination of an active pharmaceutical ingredient, as defined in
621 paragraph (2), with another component of a drug product for purposes of
622 production of such a drug product.
623
- 624 (7) **Generic Drug Submission** means an abbreviated new drug application, an
625 amendment to an abbreviated new drug application, or a prior approval
626 supplement to an abbreviated new drug application.
627
- 628 (8) **Human generic drug activities** means the following activities of the Secretary
629 associated with generic drugs and inspection of facilities associated with generic
630 drugs:
631 (A) The activities necessary for the review of generic drug submissions,
632 including review of drug master files referenced in such submissions.
633 (B) The issuance of approval letters which approve abbreviated new drug
634 applications or supplements to such applications or complete response
635 letters which set forth in detail the specific deficiencies in such

- 636 applications and, where appropriate, the actions necessary to place such
637 applications in condition for approval.
- 638 (C) The issuance of letters related to Type II active pharmaceutical drug
639 master files which set forth in detail the specific deficiencies in such
640 submissions and, where appropriate, the actions necessary to resolve those
641 deficiencies or, if appropriate, document that no deficiencies need to be
642 addressed.
- 643 (D) Inspections related to generic drugs.
- 644 (E) Monitoring of research conducted in connection with the review of generic
645 drug submissions and drug master files.
- 646 (F) Postmarket safety activities with respect to drugs approved under
647 abbreviated new drug applications or supplements, including the following
648 activities:
- 649 (i) Collecting, developing, and reviewing safety information on
650 approved drugs, including adverse event reports.
- 651 (ii) Developing and using improved adverse-event data-collection
652 systems, including information technology systems.
- 653 (iii) Developing and using improved analytical tools to assess potential
654 safety problems, including access to external data bases.
- 655 (iv) Implementing and enforcing section 505(o) [21 USC § 355(o)]
656 (relating to postapproval studies and clinical trials and labeling
657 changes) and section 505(p) [21 USC § 355(p)] (relating to risk
658 evaluation and mitigation strategies) insofar as those activities
659 relate to abbreviated new drug applications.
- 660 (v) Carrying out section 505(k)(5) [21 USC § 355(k)(5)] (relating to
661 adverse event reports and postmarket safety activities).
- 662 (G) Regulatory science activities related to generic drugs.
- 663
- 664 (9) **Prior Approval Supplement** means a request to the Secretary to approve a
665 change in the drug substance, drug product, production process, quality controls,
666 equipment, or facilities covered by an approved abbreviated new drug application when
667 that change has a substantial potential to have an adverse effect on the identity, strength,
668 quality, purity, or potency of the drug product as these factors may relate to the safety or
669 effectiveness of the drug product.
- 670
- 671 (10) **Resources allocated for the human generic drug activities**, means the expenses
672 for:
- 673 (A) officers and employees of the Food and Drug Administration,
674 contractors of the Food and Drug Administration, and costs related to
675 such officers, employees, and to contracts with such contractors;
- 676 (B) management of information, and the acquisition, maintenance, and
677 repair of computer resources;
- 678 (C) leasing, maintenance, renovation, and repair of facilities and
679 acquisition, maintenance, and repair of fixtures, furniture, scientific
680 equipment, and other necessary materials and supplies; and

681 (D) collecting fees under subsection (a) and accounting for resources
682 allocated for the review of abbreviated new drug applications and
683 supplements and inspection related to generic drugs.
684

685 (11) **Submission** occurs on the date a generic drug submission or Type II
686 pharmaceutical master file arrives in the appropriate electronic portal of the Food
687 and Drug Administration or, if in paper form, at the appropriate designated
688 document room of the Food and Drug Administration.
689

690 (12) **Type II Active Pharmaceutical Ingredient Drug Master File** means a
691 submission of information to the Secretary by a person that intends to authorize the
692 Food and Drug Administration to reference the information to support approval of
693 a generic drug submission without the submitter having to disclose the information
694 to the generic drug submission applicant.
695

696 (n) **Disputes concerning fees**
697 To qualify for the return of a fee claimed to have been paid in error under this section, a
698 person shall submit to the Secretary a written request justifying such return within 180
699 calendar days after such fee was paid.
700

701 (o) **Substantially complete applications.** – An abbreviated new drug application that is not
702 considered to be received within the meaning of section 505(j)(5)(A) because of failure to
703 pay an applicable fee under this provision within the time period specified in subsection (g)
704 shall be deemed not to have been “substantially complete” on the date of its submission
705 within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application
706 that is not substantially complete on the date of its submission solely because of failure to
707 pay an applicable fee under the preceding sentence shall be deemed substantially complete
708 and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is
709 received.”.
710

711 **SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.**

712 Part 8 of subchapter C of chapter VII, as added by section 102, is amended by inserting after
713 section 744G the following:
714

715 **"SEC. 744H. REAUTHORIZATION; REPORTING REQUIREMENTS.**

716
717 (a) **PERFORMANCE REPORT.**—Beginning with fiscal year 2013,
718 not later than 120 days after the end of each fiscal year for which
719 fees are collected under this part, the Secretary shall prepare and
720 submit to the Committee on Energy and Commerce of the House
721 of Representatives and the Committee on Health, Education, Labor,
722 and Pensions of the Senate a report concerning the progress of
723 and Pensions of the Senate a report concerning the progress of
724 the Food and Drug Administration in achieving the goals identified
725

726 in the letters described in section 101(c) of the Generic Drug User Fee Amendments of
727 2012 during such fiscal year and the future plans of the Food and Drug Administration
728 for meeting the goals.

729
730 (b) **FISCAL REPORT.**—Beginning with fiscal year 2013, not later
731 than 120 days after the end of each fiscal year for which fees
732 are collected under this part, the Secretary shall prepare and submit
733 to the Committee on Energy and Commerce of the House of Representatives
734 and the Committee on Health, Education, Labor, and
735 Pensions of the Senate a report on the implementation of the
736 authority for such fees during such fiscal year and the use, by
737 the Food and Drug Administration, of the fees collected for such
738 fiscal year.

739
740 (c) **PUBLIC AVAILABILITY.**—The Secretary shall make the
741 reports required under subsections (a) and (b) available to the
742 public on the Internet Web site of the Food and Drug Administration.

743
744 (d) **REAUTHORIZATION.**—

745
746 (1) **CONSULTATION.**—In developing recommendations to
747 present to the Congress with respect to the goals, and plans
748 for meeting the goals, for human generic
749 drug activities for the first 5 fiscal years after fiscal year
750 2017, and for the reauthorization of this part for such fiscal
751 years, the Secretary shall consult with—

- 752 (A) the Committee on Energy and Commerce of the
- 753 House of Representatives;
- 754 (B) the Committee on Health, Education, Labor, and
- 755 Pensions of the Senate;
- 756 (C) scientific and academic experts;
- 757 (D) health care professionals;
- 758 (E) representatives of patient and consumer advocacy
- 759 groups; and
- 760 (F) the generic drug industry.

761
762 (2) **PRIOR PUBLIC INPUT.**—Prior to beginning negotiations
763 with the generic drug industry on the reauthorization of this part,
764 the Secretary shall—

- 765 (A) publish a notice in the Federal Register requesting
- 766 public input on the reauthorization;
- 767 (B) hold a public meeting at which the public may
- 768 present its views on the reauthorization, including specific
- 769 suggestions for changes to the goals referred to in subsection
- 770 (a);
- 771 (C) provide a period of 30 days after the public meeting

772 to obtain written comments from the public suggesting
773 changes to this part; and
774 (D) publish the comments on the Food and Drug
775 Administration's Internet Web site.
776
777 (3) **PERIODIC CONSULTATION.**—Not less frequently than
778 once every month during negotiations with the generic drug
779 industry, the Secretary shall hold discussions with representatives
780 of patient and consumer advocacy groups to continue
781 discussions of their views on the reauthorization and their
782 suggestions for changes to this part as expressed under paragraph
783 (2).
784
785 (4) **PUBLIC REVIEW OF RECOMMENDATIONS.**—After negotiations
786 with the generic drug industry, the Secretary shall—
787 (A) present the recommendations developed under
788 paragraph (1) to the Congressional committees specified
789 in such paragraph;
790 (B) publish such recommendations in the Federal Register;
791 (C) provide for a period of 30 days for the public
792 to provide written comments on such recommendations;
793 (D) hold a meeting at which the public may present
794 its views on such recommendations; and
795 (E) after consideration of such public views and comments,
796 revise such recommendations as necessary.
797
798 (5) **TRANSMITTAL OF RECOMMENDATIONS.**—Not later than
799 January 15, 2017 the Secretary shall transmit to the Congress
800 The revised recommendations under paragraph (4), a summary
801 of the views and comments received under such paragraph,
802 and any changes made to the recommendations in response
803 to such views and comments.
804
805 (6) **MINUTES OF NEGOTIATION MEETINGS.**—
806 (A) **PUBLIC AVAILABILITY.**—Before presenting the recommendations
807 developed under paragraphs (1) through (5)
808 to the Congress, the Secretary shall make publicly available,
809 on the public Web site of the Food and Drug Administration,
810 minutes of all negotiation meetings conducted
811 under this subsection between the Food and Drug Administration
812 and the generic drug industry.
813 (B) **CONTENT.**—The minutes described under subparagraph
814 (A) shall summarize any substantive proposal made
815 by any party to the negotiations as well as significant
816 controversies or differences of opinion during the negotiations
817 and their resolution."

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SEC. 104. SUNSET DATES.

(a) **AUTHORIZATION.**—The amendments made by section 102 cease to be effective October 1, 2017.

(b) **REPORTING REQUIREMENTS.**—The amendments made by section 103 cease to be effective January 31, 2018.

SEC. 105. EFFECTIVE DATE.

The amendments made by this Act shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under section 102 shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after October 1, 2012, regardless of the date of enactment of this Act.

SEC. 106. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following new subsection):

“(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744G(a)(4) or for which identifying information required by section 744G(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.”.

SEC.107. ELECTRONIC SUBMISSION OF APPLICATIONS.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 745 the following new section:

“SEC. 745A [(21 U.S.C. 379I) – Electronic Submission of Applications:

“Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under section 505(j) shall be submitted in such electronic format as specified by the Secretary in such guidance. In such guidance, the Secretary may provide a timetable for establishment by the Secretary of further standards for such electronic submission, and set forth criteria for waivers of and exemptions from the requirements of this section. This section shall not apply to submissions described in section 561.”.

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SEC.108. STREAMLINED HIRING AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

“SEC. 714. STREAMLINED HIRING AUTHORITY.

“(a) **IN GENERAL.**---In addition to any other personnel authorities, the Secretary may, without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

“(b) **ACTIVITIES DESCRIBED.**---The activities described in this subsection are activities under this Act related to human generic drug activities, as defined in section 744G (m)(8).

“(c) **OBJECTIVES SPECIFIED.**---The objectives specified in this subsection are the performance goals with respect to section 744G (regarding assessment and use of human generic drug fees), as set forth in letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as published in the Congressional Record.

“(d) **INTERNAL CONTROLS.**---The Secretary shall institute appropriate internal controls for appointments under this section.

“(e) **SUNSET.**--- The authority to appoint employees under this section shall terminate on the date that is three years after the date of enactment of this section.”.