
Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act

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DRAFT GUIDANCE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)**

**November 2020
Biosimilars**

Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act

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1 **Biosimilarity and Interchangeability: Additional Draft Q&As on**
2 **Biosimilar Development and the BPCI Act**
3 **Guidance for Industry¹**
4

5
6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
11

12
13
14 **INTRODUCTION**
15

16 This draft guidance document provides answers to common questions from prospective
17 applicants and other interested parties regarding the Biologics Price Competition and Innovation
18 Act of 2009 (BPCI Act). The question and answer (Q&A) format is intended to inform
19 prospective applicants and facilitate the development of *proposed biosimilar products* and
20 *proposed interchangeable products*,² as well as describe FDA's interpretation of certain statutory
21 requirements added by the BPCI Act.
22

23 The BPCI Act created an abbreviated licensure pathway in section 351(k) of the Public Health
24 Service Act (PHS Act) for biological products shown to be biosimilar to, or interchangeable
25 with, an FDA-licensed biological reference product (see sections 7001 through 7003 of the
26 Patient Protection and Affordable Care Act (Pub. L. 111-148) (ACA)). FDA believes that
27 guidance for industry that provides answers to commonly asked questions regarding FDA's
28 interpretation of the BPCI Act will enhance transparency and facilitate the development and
29 approval of biosimilar and interchangeable products. In addition, these Q&As respond to
30 questions the Agency has received from applicants regarding the submission of biologics license
31 applications (BLAs) for biosimilar and interchangeable products. FDA may provide additional
32 Q&As through draft guidance as appropriate.
33

¹ This draft guidance has been prepared by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA or the Agency). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

² In this draft guidance, the following terms are used to describe biological products licensed under section 351(k) of the Public Health Service Act (PHS Act): (1) *biosimilar* or *biosimilar product* refers to a product that FDA has determined to be biosimilar to the reference product (see sections 351(i)(2) and 351(k)(2) of the PHS Act) and (2) *interchangeable biosimilar* or *interchangeable product* refers to a biosimilar product that FDA has also determined to be interchangeable with the reference product (see sections 351(i)(3) and 351(k)(4) of the PHS Act). The terms *proposed biosimilar product* and *proposed interchangeable product* are used to describe a product that is under development or is the subject of a pending 351(k) BLA. Biosimilarity, interchangeability, and related issues are discussed in more detail in the BACKGROUND section of this draft guidance.

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34 The Q&As in this guidance will be finalized by adding them, as a revision, to the final guidance
35 document *Questions and Answers on Biosimilar Development and the BPCI Act* as appropriate.
36 The final guidance document is part of a series of guidance documents that FDA developed to
37 facilitate development of biosimilar and interchangeable products.

38
39 The final guidance documents issued to date address a broad range of issues, including:

- 40 • *Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference*
41 *Product* (December 2016)
- 42 • *Considerations in Demonstrating Interchangeability With a Reference Product* (May
43 2019)
- 44 • *Labeling for Biosimilar Products* (July 2018)
- 45 • *Questions and Answers on Biosimilar Development and the BPCI Act (Revision 1)*
46 (December 2018)
- 47 • *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (April
48 2015)

49
50 In addition, FDA has published draft guidance documents related to the BPCI Act, which, when
51 finalized, will represent FDA’s current thinking. These draft guidance documents include:

- 52 • *Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment*
53 *and Other Quality-Related Considerations* (May 2019)
- 54 • *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products*
55 (June 2018)
- 56 • *New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)*
57 (December 2018)
- 58 • *Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the*
59 *PHS Act* (August 2014)

60
61 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
62 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
63 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
64 the word *should* in Agency guidances means that something is suggested or recommended, but
65 not required.

66
67

BACKGROUND

68
69
70 *The BPCI Act*

71
72 The BPCI Act was enacted as part of the ACA on March 23, 2010. The BPCI Act amended the
73 PHS Act and other statutes to create an abbreviated licensure pathway for biological products
74 shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product

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75 (see sections 7001 through 7003 of the ACA). Section 351(k) of the PHS Act (42 U.S.C.
76 262(k)), added by the BPCI Act, sets forth the requirements for the licensure of a proposed
77 biosimilar or proposed interchangeable product.

78
79 Section 351(i) defines *biosimilarity* to mean “that the biological product is highly similar to the
80 reference product notwithstanding minor differences in clinically inactive components” and that
81 “there are no clinically meaningful differences between the biological product and the reference
82 product in terms of the safety, purity, and potency of the product” (see section 351(i)(2) of the
83 PHS Act).

84
85 A BLA submitted under section 351(k) (a “351(k) BLA”) must contain, among other things,
86 information demonstrating that the biological product is biosimilar to a reference product based
87 upon data derived from analytical studies, animal studies, and a clinical study or studies (see
88 section 351(k)(2)(A)(i)(I) of the PHS Act), unless FDA has determined that an element described
89 in section 351(k)(2)(A)(i)(I) is unnecessary (see section 351(k)(2)(A)(ii) of the PHS Act). To
90 meet the standard for “interchangeability,” an applicant must provide sufficient information to
91 demonstrate biosimilarity to the reference product and also to demonstrate that the biological
92 product can be expected to produce the same clinical result as the reference product in any given
93 patient, and if the biological product is administered more than once to an individual, the risk in
94 terms of safety or diminished efficacy of alternating or switching between the use of the
95 biological product and the reference product is not greater than the risk of using the reference
96 product without such alternation or switch (see section 351(k)(4) of the PHS Act).
97 Interchangeable products may be substituted for the reference product without the intervention of
98 the prescribing healthcare provider (see section 351(i)(3) of the PHS Act).

99
100 *Biosimilar Development and the BPCI Act “Question and Answer” Guidance Format*

101
102 FDA has been using the format of Q&A guidance to describe the Agency’s thinking on and
103 update certain information and recommendations relevant to the development of biosimilar and
104 interchangeable products. This draft guidance includes only Q&As that are in draft form. The
105 guidance *Questions and Answers on Biosimilar Development and the BPCI Act* contains all
106 Q&As that are final. As FDA issues individual Q&As, they will first be incorporated into a draft
107 Q&A guidance document, as is being done in this draft guidance. After FDA has considered any
108 comments on draft Q&As received during the relevant comment period and, as appropriate,
109 incorporated suggested changes to the Q&A, individual Q&As will be finalized and moved to
110 the final guidance document.

111
112 A Q&A that was previously in the final guidance document may be withdrawn and moved to a
113 draft guidance document if FDA determines that the Q&A should be revised in some respect and
114 reissued in a revised draft Q&A for comment. A Q&A also may be withdrawn and removed
115 from the Q&A guidance documents if, for instance, the issue addressed in the Q&A is addressed
116 in another FDA guidance document. No such changes to currently issued draft or final guidance
117 documents are being made in connection with the issuance of this draft guidance.

118
119 FDA will provide the publication date of the current version of each Q&A, and information
120 about whether the Q&A has been added to or modified in the relevant draft guidance document.

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121 FDA has maintained the original numbering of the guidance Q&As used in the December 2018
122 final guidance document (*Questions and Answers on Biosimilar Development and the BPCI Act*)
123 and December 2018 draft guidance document (*New and Revised Draft Q&As on Biosimilar*
124 *Development and the BPCI Act (Revision 2)*). For ease of reference, a Q&A retains the same
125 number when it moves from a draft guidance document to the final guidance document and,
126 where appropriate, when a Q&A is withdrawn from the final guidance document and moved to a
127 draft guidance document.

128
129 Where a Q&A has been withdrawn from the final guidance document, this is marked in the final
130 guidance document by several asterisks between nonconsecutively numbered Q&As, and where
131 appropriate, explanatory text.

132
133

QUESTIONS AND ANSWERS

134

I. BIOSIMILARITY OR INTERCHANGEABILITY

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141 ***Q.I.25 How may the applicant seek FDA review for licensure for an interchangeable***
142 ***biosimilar, and how does FDA intend to review an application submitted under***
143 ***section 351(k) that seeks licensure as an interchangeable biosimilar and includes***
144 ***data and information sufficient to support licensure of the product as a biosimilar***
145 ***product, but does not contain data and information sufficient to support licensure***
146 ***of the product as an interchangeable biosimilar?***
147 ***[New November 2020]***

148

149 A.I.25 To support licensure of an interchangeable biosimilar under section 351(k) of the PHS
150 Act, an applicant must show that the product meets the standards described in section
151 351(k)(4).³ Among the specified criteria that must be met to be licensed as an
152 interchangeable biosimilar under section 351(k)(4), the applicant must show that the
153 biological product is “biosimilar to the reference product.” Thus, there may be
154 situations in which the data and information provided in a BLA seeking licensure as
155 an interchangeable biosimilar can support licensure of the product as a biosimilar
156 product but not as an interchangeable biosimilar.

157

158 As an initial matter, if a BLA submitted under section 351(k) of the PHS Act is
159 intended to support licensure as an interchangeable biosimilar, the BLA submission

³ In addition to the requirement under section 351(k)(4) that FDA determine that the information submitted in the application or the supplement is sufficient to show that the biological product “is biosimilar to the reference product,” FDA must also find that the proposed product “can be expected to produce the same clinical result as the reference product in any given patient,” and that “for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch” in order to license the proposed product as an interchangeable biosimilar.

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160 should contain an affirmative statement to that effect. If a BLA submission does not
161 contain such a statement, the Agency plans to evaluate the BLA for licensure only as
162 a biosimilar product. In other words, the Agency intends to evaluate whether the
163 proposed product meets the requirements for licensure as an interchangeable
164 biosimilar only if the 351(k) BLA indicates at the time of submission that it contains
165 information intended to demonstrate that the product meets the standards described in
166 section 351(k)(4) for licensure as an interchangeable biosimilar. This approach
167 provides for a more efficient and predictable review of BLAs.

168
169 If an applicant indicates in its cover letter that a BLA submitted under section 351(k)
170 contains information intended to demonstrate interchangeability, the Agency
171 generally plans to evaluate the BLA as both an application for licensure of a
172 biosimilar product and an application for licensure of an interchangeable biosimilar.
173 In such cases, if a BLA submitted under section 351(k) contains data and information
174 sufficient to support licensure of the product as a biosimilar product but does not
175 contain data and information sufficient to support licensure of the product as an
176 interchangeable biosimilar as a scientific matter, FDA intends to split the application
177 for administrative purposes. This will enable the Agency to take separate actions on
178 such a BLA as appropriate. For example, FDA could license the product as a
179 biosimilar product⁴ and convey deficiencies in the application for licensure as an
180 interchangeable biosimilar to the applicant in a complete response letter, and FDA
181 could make a determination of interchangeability for the product upon submission of
182 a supplement that contains all data and information necessary to support licensure of
183 the product as an interchangeable biosimilar.⁵

184
185 However, if an applicant specifically requests that the Agency approve an application
186 for licensure submitted under 351(k) only if FDA determines the product to be
187 interchangeable with the reference product, the Agency plans to evaluate only
188 whether the application for the biological product meets the standards described in
189 section 351(k)(4) for licensure as an interchangeable biosimilar (an “interchangeable-
190 only” review). The Agency recommends that an applicant requesting this type of
191 review clearly note the request for “INTERCHANGEABLE-ONLY REVIEW” in the
192 cover letter accompanying the BLA. If upon an “interchangeable-only” review the
193 Agency determines that a BLA is not approvable for licensure as an interchangeable
194 biosimilar, the Agency intends to send a complete response letter addressing the
195 request for licensure as an interchangeable biosimilar.⁶ The complete response letter
196 would also include deficiencies pertaining to a demonstration of biosimilarity, if any,
197 because biosimilarity is a condition necessary for approval of a 351(k) BLA as an
198 interchangeable product. Consistent with the applicant’s request, however, the
199 complete response letter would not address whether the application was sufficient to
200 support a demonstration of licensure as a biosimilar product alone. Upon receipt of

⁴ Section 351(k)(3) of the PHS Act. 21 CFR 601.4.

⁵ 21 CFR 601.3.

⁶ See 21 CFR 601.3.

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201 an “interchangeable-only” complete response letter, the applicant may then choose to
202 amend and resubmit their application to address the deficiencies and support a
203 demonstration of interchangeability or to amend and resubmit their BLA seeking
204 licensure as a biosimilar product.⁷
205
206

207 ***Q.I.26 How should a 351(a) BLA holder proceed if it seeks licensure of its biological***
208 ***product under section 351(k) as biosimilar to or interchangeable with another***
209 ***biological product licensed under section 351(a) (a “reference product”)?***
210 ***[New November 2020]***
211

212 A.I.26 FDA reviews data and information intended to support licensure of a proposed
213 biological product as a biosimilar product in an original application submitted under
214 section 351(k) of the PHS Act.⁸ Similarly, FDA reviews data and information
215 intended to support licensure of a proposed biological product as an interchangeable
216 biosimilar in an original application submitted under section 351(k) of the PHS Act or
217 a supplement to an approved application submitted under section 351(k) of the PHS
218 Act.⁹ Therefore, if a holder of a BLA for a biological product licensed or deemed
219 licensed¹⁰ under section 351(a) wishes to submit an application for licensure of that
220 biological product as a biosimilar to or interchangeable with another biological
221 product, i.e. the reference product, it should do so by submitting an original
222 application for licensure under section 351(k).
223

224 As with any application under section 351(k), such an application should specify the
225 single biological product licensed or deemed licensed under section 351(a) of the
226 PHS Act as the reference product, as that term is defined in section 351(i), against
227 which the proposed biosimilar or proposed interchangeable product will be evaluated.
228 The application for licensure under section 351(k) also should include data and
229 information sufficient to demonstrate biosimilarity,¹¹ and, if interchangeability is
230 sought, interchangeability with the specified reference product.¹²

⁷ See 21 CFR 601.3.

⁸ See sections 351(k)(2) and (3) of the PHS Act. See also guidance for industry *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (April 2015).

⁹ See sections 351(k)(3) and (4) of the PHS Act. See also guidance for industry *Considerations in Demonstrating Interchangeability With a Reference Product* (May 2019) (Interchangeability Guidance).

¹⁰ See guidance for industry *Interpretation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009* (December 2018).

¹¹ For more information on demonstrating biosimilarity, see draft guidance for industry *Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations* (May 2019) (this draft guidance, when finalized, will represent FDA’s current thinking on this topic) and guidance for industry *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (April 2015).

¹² For more information on interchangeability, see the Interchangeability Guidance. A biosimilar product or interchangeable biosimilar may be licensed only for conditions of use that have been previously approved for the reference product. Section 351(k)(2)(A)(i)(III) of the PHS Act. See also draft guidance for industry *Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed* (February 2020), which, when finalized, will represent FDA’s current thinking on the topic.

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231
232 An applicant may support a demonstration of biosimilarity or interchangeability
233 under section 351(k) using relevant data and information from the applicant’s own
234 351(a) BLA. It is not necessary for the holder of a 351(a) BLA for a biological
235 product licensed or deemed licensed under section 351(a) to seek revocation of its
236 351(a) license in order to submit a 351(k) application. The 351(a) BLA holder may
237 continue to market the biological product licensed or deemed licensed under section
238 351(a) while the 351(k) BLA is pending and after licensure of the biological product
239 under section 351(k).¹³

240
241 FDA believes that this approach balances the opportunity for continued innovation
242 with respect to the biological product licensed or deemed licensed under section
243 351(a) of the PHS Act while facilitating robust market competition through the
244 approval of biosimilar and interchangeable products under the 351(k) pathway.
245

246
247 ***Q.I.27 Does FDA have recommendations for labeling of interchangeable biosimilars at***
248 ***this time?***
249 ***[New November 2020]***
250

251 A.I.27 Yes. Certain principles outlined in the guidance for industry *Labeling for Biosimilar*
252 *Products* (July 2018) (*Biosimilar Labeling Guidance*) pertain to interchangeable
253 biosimilars, as described below.
254

255 For example, the *Biosimilar Labeling Guidance*¹⁴ recommends that biosimilar
256 product labeling incorporate relevant data and information from the reference product
257 labeling with appropriate modifications, such as those described in the guidance. It is
258 FDA’s view that interchangeable biosimilar labeling, like biosimilar product labeling,
259 should incorporate relevant data and information from the reference product labeling,
260 including clinical data that supported FDA’s finding of safety and effectiveness of the
261 reference product.
262

263 Additionally, the *Biosimilar Labeling Guidance* states that, as a general matter, it is
264 FDA’s view that biosimilar product labeling should not include a description of or
265 data from clinical studies conducted to support a demonstration of biosimilarity.¹⁵
266 Similarly, as a general matter, it is FDA’s view that interchangeable biosimilar
267 labeling should not include a description of or data from clinical studies conducted to
268 support a demonstration of interchangeability. Generally, such studies are not
269 designed to support an independent demonstration of safety or effectiveness of the
270 proposed interchangeable product and thus would typically not be expected to
271 facilitate an understanding of product safety and effectiveness.

¹³ 21 CFR 601.5. Each product would need to be marketed in accordance with its respective approved conditions of use, as reflected in each product’s FDA-approved product labeling.

¹⁴ See Section III in the guidance for industry *Labeling for Biosimilar Products* (July 2018).

¹⁵ *Ibid.*

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272
273 In addition, as required under 21 CFR 201.56(c)(1) and as described in the *Biosimilar*
274 *Labeling Guidance* with respect to biosimilar products, interchangeable biosimilar
275 labeling must meet the content and format requirements of the physician labeling rule
276 (PLR) as described in 21 CFR 201.56(d) and 201.57, regardless of the format of the
277 reference product labeling.¹⁶ Like biosimilar product labeling, interchangeable
278 biosimilar labeling must also meet the content and format requirements of the final
279 pregnancy and lactation labeling rule (PLLR) as described in 21 CFR 201.57(c)(9)(i)
280 through (iii), regardless of whether the reference product must meet these
281 requirements.¹⁷

282
283 Certain differences between interchangeable biosimilar and reference product
284 labeling may be appropriate. For example, as discussed in the *Biosimilar Labeling*
285 *Guidance* with respect to biosimilar products,¹⁸ interchangeable biosimilar product
286 labeling conforming to PLR and/or PLLR may differ from reference product labeling
287 because the reference product labeling may not be required to conform to those
288 requirements at the time of licensure of the interchangeable biosimilar. As an
289 additional example, it may be appropriate for interchangeable biosimilar labeling to
290 deviate from that of the reference product to the extent that an applicant chose to seek
291 licensure of the interchangeable biosimilar for fewer than all of the reference
292 product’s licensed conditions of use.¹⁹ As stated in the guidance for industry
293 *Considerations in Demonstrating Interchangeability With a Reference Product* (May
294 2019), although a sponsor may seek licensure for a proposed interchangeable product
295 for fewer than all conditions of use for which the reference product is licensed, FDA
296 recommends that a sponsor seek licensure for all of the reference product’s licensed
297 conditions of use when possible.

298
299 FDA also considers the recommendations described in sections IV through VII of the
300 *Biosimilar Labeling Guidance* to be generally applicable to interchangeable
301 biosimilars. For the recommendations regarding specific sections of biosimilar

¹⁶ *Ibid.*; see also final rule “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products” (71 FR 3922, January 24, 2006). This rule is commonly referred to as the physician labeling rule. See also additional labeling guidances at <https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources>.

¹⁷ See final rule “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling” (79 FR 72064, December 4, 2014). The final rule describes the implementation schedule for applications submitted on or after the effective date of the rule, applications pending at the time the rule became effective, and applications approved before the rule became effective (79 FR 72064 at 72095–96).

¹⁸ See section IV in the guidance for industry *Labeling for Biosimilar Products* (July 2018).

¹⁹ For additional information, see draft guidance for industry *Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed* (February 2020), which, when finalized, will represent FDA’s current thinking on the topic. FDA expects that applicants seeking to demonstrate interchangeability will submit data and information to support a showing that the proposed interchangeable product can be expected to produce the same clinical result as the reference product in all of the reference product’s licensed conditions of use. Guidance for industry *Considerations in Demonstrating Interchangeability With a Reference Product* (May 2019).

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302 product labeling outlined in section IV.C. of the *Biosimilar Labeling Guidance*, FDA
303 recommends that labeling for an interchangeable biosimilar include an
304 interchangeability statement rather than a biosimilarity statement, as discussed in
305 Q.I.28 of this guidance.

306
307 FDA intends to provide any additional recommendations for interchangeable
308 biosimilar labeling in future guidance as the Agency gains more experience with
309 interchangeable biosimilars.

310
311

312 ***Q.I.28 Does FDA recommend that the BLA-holder of an approved interchangeable***
313 ***biosimilar include a labeling statement on interchangeability?***
314 ***[New November 2020]***

315

316 A.I.28 Yes. FDA recommends including a statement, placed on the line immediately
317 beneath the Initial U.S. Approval in the Highlights of Prescribing Information
318 (Highlights), that the product is interchangeable with the reference product. It should
319 read as follows:

320

321 [INTERCHANGEABLE BIOSIMILAR'S PROPRIETARY NAME
322 (interchangeable biosimilar's proper name)] is interchangeable* with
323 [REFERENCE PRODUCT'S PROPRIETARY NAME (reference product's
324 proper name)].

325

326 The asterisk should appear as a footnote symbol inserted after the word
327 "interchangeable." For example, for the fictitious product HILEZEO, the statement
328 should read as follows:

329

330 HILEZEO (calipicamab-tlsk) is interchangeable* with CLAREXANT
331 (calipicamab-fjwo).

332

333 For a fictitious interchangeable product that does not have a proprietary name, the
334 statement should read, in regular (not bold) font, as follows:

335

336 calipicamab-tlsk is interchangeable* with CLAREXANT (calipicamab-fjwo).

337

338 The footnote should appear, in regular (not bold) font, at the end of Highlights (but
339 above the Revision Date) and state the following:

340

341 * An interchangeable product (IP) is a biological product that is approved based
342 on data demonstrating that it is highly similar to an FDA-approved reference
343 product (RP) and that there are no clinically meaningful differences between the
344 products; it can be expected to produce the same clinical result as the RP in any
345 given patient; and if administered more than once to a patient, the risk in terms of
346 safety or diminished efficacy from alternating or switching between use of the RP
347 and IP is not greater than that from the RP without such alternation or switch.

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348 Interchangeability of [INTERCHANGEABLE BIOSIMILAR’S PROPRIETARY
349 NAME] has been demonstrated for the condition(s) of use, strength(s), dosage
350 form(s), and route(s) of administration described in its Full Prescribing
351 Information.
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355 **II. PROVISIONS RELATED TO REQUIREMENTS TO SUBMIT A BLA FOR A**
356 **“BIOLOGICAL PRODUCT”**

357
358 There are no draft Q&As for this section.
359

360
361 **III. EXCLUSIVITY**

362
363 There are no draft Q&As for this section.