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# Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry

## ***DRAFT GUIDANCE***

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For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

**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)**

**May 2018  
Procedural**

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# Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry

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1       **Waivers, Exceptions, and Exemptions from the Requirements of**  
2       **Section 582 of the Federal Food, Drug, and Cosmetic Act**  
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7       This draft guidance, when finalized, will represent the current thinking of the Food and Drug  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  
16      **I.       INTRODUCTION**  
17

18      Under section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-  
19      1), trading partners<sup>2</sup> in the pharmaceutical distribution supply chain must perform specific tasks  
20      and comply with requirements to enable the traceability and security of certain prescription drugs  
21      as they are distributed in the United States. Section 582(a)(3) gives FDA the authority to grant  
22      waivers, exceptions, and exemptions from these requirements in certain situations. This guidance  
23      describes recommendations for how trading partners and stakeholders should request a waiver,  
24      exception, or exemption from the requirements of section 582 of the FD&C Act, and describes  
25      how FDA intends to review and decide such requests and determine FDA-initiated exceptions  
26      and exemptions. Additionally, this guidance describes how FDA intends to biennially review and  
27      renew waivers, exceptions, and exemptions.  
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 Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

<sup>2</sup> *Trading partner* is defined in section 581(23) of the FD&C Act and includes manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers. However, third-party logistics providers are not subject to the requirements of section 582 of the FD&C Act. For the purpose of this guidance, “trading partner” refers to manufacturers, repackagers, wholesale distributors, and dispensers.

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### 37 **II. BACKGROUND**

38  
39 The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into  
40 law on November 27, 2013. The DSCSA outlines critical steps to build an electronic,  
41 interoperable system by 2023 that is able to identify and trace products<sup>3</sup> as they are distributed in  
42 the United States. Section 202 of the DSCSA added section 582 to the FD&C Act, which sets  
43 forth trading partner requirements, including those related to product tracing, product identifiers,  
44 authorized trading partners, and verification.

45  
46 Section 582(a)(3)(A) of the FD&C Act requires FDA to issue a guidance that:

47  
48 (i) establish[es] a process by which an authorized manufacturer, repackager,  
49 wholesale distributor, or dispenser may request a waiver from any of the  
50 requirements set forth in this section, which the Secretary may grant if the  
51 Secretary determines that such requirements would result in an undue economic  
52 hardship or for emergency medical reasons,<sup>4</sup> including a public health emergency  
53 declaration pursuant to section 319 of the Public Health Service Act;

54  
55 (ii) establish[es] a process by which the Secretary determines exceptions, and a  
56 process through which a manufacturer or repackager may request such an  
57 exception, to the requirements relating to product identifiers if a product is  
58 packaged in a container too small or otherwise unable to accommodate a label  
59 with sufficient space to bear the information required for compliance with this  
60 section; and

61  
62 (iii) establish[es] a process by which the Secretary may determine other products  
63 or transactions that shall be exempt from the requirements of this section.

64  
65 Accordingly, this guidance describes the processes required by the law. Additionally, as required  
66 by section 582(a)(3)(B), this guidance also includes a process for the biennial review and  
67 renewal of waivers, exceptions, and exemptions.

68  
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<sup>3</sup> *Product* is defined in section 581(13) of the FD&C Act.

<sup>4</sup> The emergency medical reason waiver described in section 582(a)(3)(A)(i) is distinct from the emergency medical reason statutory exclusions in sections 581(24)(B)(iii) and 503(e)(4)(C), and can extend to section 582 requirements not within the purview of those statutory exclusions. For purposes of the statutory exclusions in sections 581(24)(B)(iii) and 503(e)(4)(C), a public health emergency declared under section 319 of the Public Health Service Act is automatically considered an “emergency medical reason.” Upon declaration of a public health emergency, product distribution for such emergency medical reasons is excluded from the DSCSA definitions of “transaction” and “wholesale distribution.” Therefore, the DSCSA requirements related to product tracing and wholesale distribution do not apply to trading partner activities that address the public health emergency declaration for the duration of the declaration. For more information, please visit <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm580386.htm>.

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### 70 **III. PROCESS FOR REQUESTING A WAIVER, EXCEPTION, OR EXEMPTION**

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#### 72 **A. Submitting a Request to FDA**

73

74 A trading partner or stakeholder seeking a waiver, exception, or exemption from requirements of  
75 section 582 of the FD&C Act should submit a written request to FDA.

76

#### 77 *Submissions to FDA for CBER-regulated Products*

78

79 Waiver, exception, and exemption requests for products reviewed by CBER should be submitted  
80 as product correspondence to the biologics license application (BLA), new drug application  
81 (NDA), abbreviated new drug application (ANDA), or investigational new drug application  
82 (IND) in the electronic common technical document (eCTD) format.<sup>5</sup> For submissions related  
83 exclusively to CBER-regulated products but not associated with a specific application(s),  
84 requests should be sent to [DSCSA-CBER-WEER@fda.hhs.gov](mailto:DSCSA-CBER-WEER@fda.hhs.gov). Paper submissions should be  
85 submitted to the following address:

86

87 Food and Drug Administration  
88 Center for Biologics Evaluation and Research  
89 Document Control Center  
90 10903 New Hampshire Ave.  
91 Bldg. 71, Rm. G112  
92 Silver Spring, MD 20993-0002

93

#### 94 *Submissions to FDA for all other Requests*

95

96 All other waiver, exception, and exemption requests, including those for CDER-regulated  
97 products, those that are not related to specific products, or where the lead center is uncertain or  
98 unknown, should be submitted by email to [DSCSA-WEER@fda.hhs.gov](mailto:DSCSA-WEER@fda.hhs.gov) or by mail or delivery  
99 service to the following address:

100

101 Office of Drug Security, Integrity, and Response  
102 Center for Drug Evaluation and Research  
103 Food and Drug Administration  
104 10903 New Hampshire Ave.  
105 Bldg. 51, Rm. 4203  
106 Silver Spring, MD 20993-0002  
107 Attn: DSCSA WEER team

108

109 A table summarizing where requests should be sent is provided in the Appendix.

110

111 Only an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a  
112 waiver under section 582(a)(3)(A)(i), and only a manufacturer or repackager may request an

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<sup>5</sup> See Final Guidance for Industry: *Providing Regulatory Submissions in Electronic Format – eCTD Specifications* at <https://www.fda.gov/ectd>.

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113 exception under section 582(a)(3)(A)(ii).<sup>6</sup> Any interested stakeholder may request an exemption  
114 under section 582(a)(3)(A)(iii).

115  
116 Each request should include the following information:

- 117
- 118 • The name, telephone number, and email address of an individual who FDA can contact  
119 about matters relating to the proposed waiver, exception, or exemption<sup>7</sup>
- 120 • The identity of the trading partner(s) that would be covered by the proposed waiver,  
121 exception, or exemption
- 122 • A description of the activities and/or products (including the national drug code number)  
123 for which the proposed waiver, exception, or exemption is being sought
- 124 • The requested effective period of the waiver, exception, or exemption
- 125 • The requirements of section 582 of the FD&C Act to which the proposed waiver,  
126 exception, or exemption would apply
- 127 • A detailed statement of the reasons why FDA should grant the proposed waiver,  
128 exception, or exemption, including pertinent supporting documentation
- 129

130 In addition, please include the following affirmation in your request: “I affirm that the  
131 information in this statement is correct, and I understand that under 18 U.S.C. 1001 it is illegal to  
132 make a materially false, fictitious, or fraudulent statement or representation in this matter within  
133 FDA’s jurisdiction.”

134  
135 Upon receipt of a request, FDA intends to issue an acknowledgement to the trading partner or  
136 stakeholder that submitted the request.

### **B. FDA Review of Requests**

137  
138  
139  
140 FDA intends to evaluate a request to ensure that it contains sufficient information to permit a  
141 substantive review by the Agency. If FDA determines that a request lacks sufficient information  
142 to permit a substantive review, the Agency may deny the request. FDA may also contact a  
143 requesting trading partner or stakeholder to clarify an aspect of the request (e.g., the products  
144 covered by the request) or to ask for additional information related to the subject of the request.

145  
146 During the review, FDA intends to consult with subject matter experts within the Agency as  
147 appropriate and assess, as applicable, whether:

- 148
- 149 • A waiver of the section 582 requirement(s) identified in the request is (1) warranted  
150 because complying with the requirement(s) would result in undue economic hardship or  
151 (2) appropriate for emergency medical reasons
- 152 • An exception to the section 582 requirements relating to product identifiers is warranted  
153 because the product identified in the request is packaged in a container that is too small or

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<sup>6</sup> Authorized representatives of a trading partner, such as legal counsel and consultants, may submit a waiver or exception request on behalf of the trading partner.

<sup>7</sup> It is the responsibility of the requesting trading partner or stakeholder to inform FDA of changes in contact information.

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154 otherwise unable to accommodate a label with sufficient space to bear the information  
155 required for compliance with these requirements

- 156 • Exempting the product(s) and/or transaction(s) identified in the request from the section  
157 582 requirement(s) identified in the request is appropriate to maintain public health or is  
158 otherwise appropriate

159  
160 FDA intends to also consider the potential risks that a proposed waiver, exception, or exemption  
161 poses to the security of the drug supply chain when reviewing requests. Additionally, if the  
162 submission seeks a waiver, exception, or exemption that will cover a broad segment(s) of  
163 industry and/or multiple trading partners, FDA may deny or defer the request if it determines that  
164 an FDA-initiated exception, exemption, or other regulatory action would be more appropriate.  
165 To minimize the potential risks to the drug supply chain, FDA expects to limit the duration of the  
166 waivers, exceptions, or exemptions that it grants. However, FDA may grant a waiver, exception,  
167 or exemption that is valid until further notice from the Agency to address situations that involve  
168 extraordinary circumstances.

### **C. FDA Determinations on Requests**

169  
170  
171  
172 FDA intends to notify the requesting trading partner or stakeholder of a waiver, exception, or  
173 exemption request in writing of the Agency's determination to grant, deny, or take other  
174 appropriate action on the request, and explain the basis of the determination. The Agency may, in  
175 its discretion, post information regarding a determination to its website if it concludes that doing  
176 so is in the best interest of, or is necessary to protect, public health. Such information would be  
177 posted in a manner that is consistent with the laws and regulations regarding the disclosure of  
178 confidential information.

### **D. Notifying FDA of Material Changes**

179  
180  
181  
182 A recipient of a waiver, exception, or exemption should notify the FDA Center that originally  
183 issued the waiver, exception or exemption whenever there is a material change in the  
184 circumstances that were the basis for granting the initial request for relief. Furthermore,  
185 recipients should notify FDA within a reasonable amount of time of the change; this is true  
186 regardless of the duration of the waiver, exception, or exemption. The following example is  
187 provided to help trading partners and stakeholders understand when they should notify FDA of a  
188 material change:

189  
190 A manufacturer receives an exception from FDA for a product packaged in a container  
191 that is too small to accommodate a label with space to bear a product identifier. The  
192 exception has an effective period of 3 years. A year after receiving the exception, the  
193 manufacturer begins packaging the product in a larger container that is able to  
194 accommodate a label with space for a product identifier. The manufacturer should notify  
195 FDA of this change when it begins production with the new container instead of waiting  
196 until the biennial review of the exception.

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### **199 IV. PROCESS FOR FDA-INITIATED EXCEPTIONS AND EXEMPTIONS**

200  
201 Sections 582(a)(3)(A)(ii) and (iii) of the FD&C Act give FDA the authority to establish  
202 exceptions or exemptions from the requirements of section 582 on its own initiative. FDA  
203 intends to use this authority when necessary to address an issue that affects a broad segment(s) of  
204 industry and/or multiple trading partners, impacts many activities, or involves numerous  
205 products. Consistent with the approach described in Section III, FDA intends to only establish  
206 exceptions under section 582(a)(3)(A)(ii) on its own initiative where it is assessed that the  
207 excepted product(s) is packaged in a container that is too small or otherwise unable to  
208 accommodate a label with sufficient space to bear the information required for compliance with  
209 the section 582 requirements relating to product identifiers. Similarly, FDA intends to only  
210 establish exemptions under section 582(a)(3)(A)(iii) on its own initiative where it determines that  
211 the exemption is appropriate to maintain public health or is otherwise appropriate. As with  
212 exceptions and exemptions that are granted pursuant to a request, before establishing exceptions  
213 or exemptions, FDA intends to consider how an exception or exemption might affect the security  
214 of the drug supply chain prior to establishing the exception or exemption on its own initiative.  
215

216 If FDA establishes an exception or exemption to address a particular issue, it intends to  
217 communicate the information in writing using a method appropriate for the circumstances (e.g., a  
218 letter to the affected trading partners or - if an exception or exemption applied to a broad  
219 segment of industry - a posting on its website). An exception or exemption that is established by  
220 FDA may be limited in duration or valid until further notice from FDA.  
221

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224

### **V. REVIEW AND RENEWAL OF WAIVERS, EXCEPTIONS, AND EXEMPTIONS**

225

#### **A. Biennial Review of Waivers, Exceptions, and Exemptions**

226

227  
228 Once every 2 years, FDA intends to review waivers, exceptions, and exemptions that are valid  
229 until further notice from the Agency or longer than 2 years in duration (i.e., the expiration date is  
230 more than 2 years after the effective date) and renew such waivers, exceptions, and exemptions,  
231 as applicable. During this review, the Agency intends to assess whether there has been a  
232 material change in circumstances such that the waiver, exception, or exemption is no longer  
233 appropriate. If the waiver, exception, or exemption under review is one that the Agency granted  
234 in response to a written request, FDA may seek the recipient's assistance in determining whether  
235 there has been a material change in circumstances. For example, a trading partner that received  
236 an "undue economic hardship" waiver may be asked to submit updated financial information  
237 demonstrating that the circumstances supporting the original waiver decision still exist.  
238

239

240 In the event FDA determines that a waiver, exception, or exemption is no longer appropriate  
241 following a biennial review, it intends to terminate the waiver, exception, or exemption. For  
242 waivers, exceptions, and exemptions that were granted in response to a written request, FDA  
243 intends to provide written notice of its determination to the recipient of the waiver, exception, or  
244 exemption. For FDA-initiated exceptions and exemptions, the Agency intends to announce the  
245 termination using a written method appropriate for the circumstances. The Agency intends to

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245 issue these written notices and announcements within a reasonable amount of time before the  
246 stated termination date.

247

### **B. Renewal of Expiring Waivers, Exceptions, and Exemptions**

249

250 A trading partner or stakeholder may submit a renewal request for any waiver, exception, or  
251 exemption it received that is of limited duration. A renewal request should be submitted to the  
252 FDA Center that originally issued the waiver, exception or exemption as soon as the trading  
253 partner or stakeholder determines that renewal is necessary. The request should include a  
254 detailed statement justifying the continuance of the waiver, exception, or exemption, and the  
255 desired length of the extension. In addition, the request should contain the affirmation set forth in  
256 Section III.A. FDA intends to review and respond to renewal requests in the same manner that it  
257 reviews and responds to initial requests for waivers, exceptions, and exemptions.<sup>8</sup>

258

259 FDA does not intend to accept a renewal request for an FDA-initiated exception or exemption. If  
260 a trading partner believes that it will need to renew an expiring FDA-initiated exception or  
261 exemption after the expiration date, that trading partner or stakeholder should submit a written  
262 request for an exception or exemption in accordance with the process set forth in Section III of  
263 this guidance.

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<sup>8</sup> See Sections III.B and III.C of this guidance.

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**APPENDIX**

**Where to Submit Waiver, Exception, and Exemption Requests**

	<b>Electronic Submissions to FDA</b>	<b>Paper Submissions to FDA (if electronic submissions are not possible)</b>
<b>Requests related exclusively to CBER-regulated products that are associated with a BLA, NDA, ANDA, or IND</b>	Send in eCTD format to FDA Electronic Submission Gateway as product correspondence	N/A
<b>Requests related exclusively to CBER-regulated products that are <i>not</i> associated with a specific application(s)</b>	Send email to:  <u><a href="mailto:DSCSA-CBER-WEER@fda.hhs.gov">DSCSA-CBER-WEER@fda.hhs.gov</a></u>	Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Ave. Bldg. 71, Rm. G112 Silver Spring, MD 20993-0002 Attn: CBER OCBQ
<b>All other requests, including those for CDER-regulated products, those that are not related to specific products, or when the lead center is uncertain or unknown</b>	Send email to:  <u><a href="mailto:DSCSA-WEER@fda.hhs.gov">DSCSA-WEER@fda.hhs.gov</a></u>	Office of Drug Security, Integrity, and Response Center for Drug Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 51, Rm. 4203 Silver Spring, MD 20993-0002 Attn: DSCSA WEER team

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