
Guidance for Industry

Bar Code Label Requirements

Questions and Answers

DRAFT GUIDANCE

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

**June 2005
Compliance**

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Center for Drug Evaluation and Research (CDER)
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Table Of Contents

1
2

3 **I. INTRODUCTION..... 1**

4 **II. BACKGROUND 1**

5 **III. QUESTIONS AND ANSWERS..... 2**

6 **WHO IS SUBJECT TO THE BAR CODE RULE? 2**

7 *Q1: Is a firm subject to the bar code rule if it sells its drugs to distributors, and the*

8 *distributor then sells it to others (including hospitals)? 2*

9 *Q2: If a distributor merely distributes a product and does nothing to the drug itself, is the*

10 *distributor subject to the bar code requirements?..... 2*

11 **EXEMPTIONS 2**

12 *Q3: Are OTC drugs that are packaged in LDPE (low-density polyethylene) containers and*

13 *are commonly used in hospitals and dispensed pursuant to an order exempt from the*

14 *bar code rule?..... 2*

15 *Q4: Can a firm whose products have a very low rate of medication errors obtain*

16 *exemptions for those products? 3*

17 *Q5: Can drugs such as suppositories be exempt from the bar code requirements due to their*

18 *small container size or their container material (including foil wrap)?..... 3*

19 *Q6: Does the bar code rule require hospitals to affix bar codes on drugs?..... 3*

20 **IMPLEMENTATION DATES 4**

21 *Q7: How is the 2-year implementation date intended to work? 4*

22 *Q8: Does the product expiration date have any bearing on the bar code requirements? 4*

23 *Q9: If a drug was approved before the effective date of the final rule, but a supplement is*

24 *still pending as of the effective date, what date is used to determine when the product*

25 *needs to meet the bar code requirements? 4*

26 **QUALITY, APPEARANCE, AND PLACEMENT OF THE BAR CODE 4**

27 *Q10: Can a firm use another automatic identification technology, such as a radio frequency*

28 *identification chip or a two-dimensional symbology, instead of a linear bar code? 4*

Contains Nonbinding Recommendations

Draft — Not for Implementation

29 **Q11:** *What should be used in lieu of an asterisk in an NDC?.....* 5

30 **Q12:** *If a drug product has a bar code on the immediate container and the outer container is*
31 *an overwrap through which the bar code is human-readable but not machine-readable,*
32 *does the overwrap also have to contain the bar code if the drug product is administered*
33 *without the overwrap?.....* 5

34 **Q13:** *For a product packaged in blister cells divided by perforations that enable the cells to*
35 *be separated, should there be one bar code for the entire package or does each cell*
36 *need a bar code?.....* 6

37 **Q14:** *Does FDA intend to issue guidance regarding bar code quality, such as size, symbol*
38 *quality, symbol grade, reflectance?* 6

39 **MISCELLANEOUS** 6

40 **Q15:** *Does FDA intend to buy bar code scanning equipment to promote bar code use in*
41 *hospitals?* 6

42

Guidance for Industry¹

Bar Code Label Requirements — Questions and Answers

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

FDA regulations require that certain human drug and biological product labels contain a bar code consisting of, at a minimum, the National Drug Code (NDC) number (21 CFR 201.25). This guidance provides questions and answers relating to how the bar code label requirements apply to specific products or circumstances. The questions are based on those posed to the Agency since the final rule published in February 2004.

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

II. BACKGROUND

In the *Federal Register* of February 26, 2004 (69 FR 9120), we published a final rule requiring certain human drug and biological products to have on their labels a linear bar code that contains, at a minimum, the drug's NDC number (21 CFR 201.25). The rule also requires the use of machine-readable information on blood and blood component labels (21 CFR 606.121(c)(13)).² Bar codes will allow health care professionals to use bar code scanning equipment to verify that

¹ This guidance has been prepared by the Office of Regulatory Policy in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration, in conjunction with the Agency's Bar-Code Working Group.

² Section 606.121 requires the container label of a blood or blood component to bear encoded information in a machine-readable format and approved for use by the Director, CBER. The questions and answers in this guidance focus on bar codes, not machine-readable labels on blood and blood components, because the questions we received focused on bar codes. The Agency may revise this guidance as we receive additional questions.

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80 the right drug (in the right dose and right route of administration) is being given to the right
81 patient at the right time. This new system is intended to help reduce the number of medication
82 errors that occur in hospitals and health care settings.
83

84 **III. QUESTIONS AND ANSWERS**

85

86 **WHO IS SUBJECT TO THE BAR CODE RULE?**

87

88 **Q1:** *Is a firm subject to the bar code rule if it sells its drugs to distributors, and the*
89 *distributor then sells it to others (including hospitals)?*

90

91 **A1:** Yes. Under § 201.25, manufacturers, repackers, relabelers, and private label
92 distributors of human prescription drug products, biological products, and over-the-
93 counter (OTC) drug products that are dispensed pursuant to an order and are
94 commonly used in hospitals are subject to the bar code requirement, regardless of the
95 method they use to distribute their drug products.
96

97

98 **Q2:** *If a distributor merely distributes a product and does nothing to the drug itself, is the*
99 *distributor subject to the bar code requirements?*

100

101 **A2:** No. Under § 201.25, manufacturers, repackers, relabelers, and private label
102 distributors of drug products covered by the bar code rule who are subject to the
103 establishment registration and drug listing requirements in section 510 of the Federal
104 Food, Drug, and Cosmetic Act (the Act) are responsible for placing the appropriate
105 bar code on the product. A distributor who does nothing to the drug itself is not
106 subject to registration and listing requirements and thus is not required to place a bar
107 code on the product. However, any drug that requires a bar code and does not have
108 one is misbranded under section 502 of the Act.
109

110

111

112 **EXEMPTIONS**

113

114 **Q3:** *Are OTC drugs that are packaged in LDPE (low-density polyethylene) containers and*
115 *are commonly used in hospitals and dispensed pursuant to an order exempt from the*
116 *bar code rule?*

117

118 **A3:** No. We intend, however, to exercise enforcement discretion by extending to OTC
119 drugs the exemption in § 201.25(b)(1)(i)(F) that applies to prescription drug products
120 in LDPE form fill and seal containers that are not packaged with an overwrap. We
121 responded to a comment on LDPE containers in the preamble to the final rule
122 (response to comment 22, 69 FR 9120 at 9129). Because the comment was presented
123 in the context of prescription drugs, our response addressed prescription drugs. The
124 technical issue (potential leaching), however, affects any drug packaged in this
manner. We will also consider amending the regulation to reflect this exemption.

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125 **Q4:** *Can a firm whose products have a very low rate of medication errors obtain*
126 *exemptions for those products?*
127

128 A4: No. A few medication errors for a particular product cannot justify an exemption. As
129 we explained in the preamble to the final rule, if the type of medication error is
130 serious, such as an error that results in death, it would be difficult to justify an
131 exemption on the grounds that few deaths occur. We also have no basis to establish a
132 threshold or baseline number of medication errors that would determine whether a
133 drug should or should not be subject to the bar code requirement. Even if we could
134 establish such a threshold or baseline figure, that figure may not be reliable because
135 health care professionals are not required to submit adverse event reports to us. In
136 other words, the adverse event reporting system can signal the possible existence of a
137 problem, but it cannot reliably predict the frequency with which such problems may
138 occur (response to comment 17, 69 FR 9120 at 9128).
139

140 **Q5:** *Can drugs such as suppositories be exempt from the bar code requirements due to their*
141 *small container size or their container material (including foil wrap)?*
142

143 A5: Not automatically. The final rule does not provide a blanket exemption for
144 suppositories or small containers. As discussed in the preamble to the final rule, we
145 declined to exclude suppositories from the bar code requirement (response to
146 comment 25, 69 FR 9120 at 9130). Furthermore, we declined to exempt small vials
147 or containers (including suppositories, prefilled syringes, and other small products)
148 and stated that firms may, alternatively, modify the drug's immediate container to
149 accommodate a label bearing a bar code (response to comment 27, 69 FR 9120 at
150 9131). A firm may apply for an exemption from the bar code requirement under
151 § 201.25(d) if it can document that putting a bar code on its particular suppository
152 product would adversely affect the product's safety, effectiveness, purity, or potency
153 or is otherwise technologically not feasible *and* the problem cannot be solved by a
154 package redesign or overwrap.
155

156 **Q6:** *Does the bar code rule require hospitals to affix bar codes on drugs?*
157

158 A6: No. The rule applies to drug manufacturers, repackers, relabelers, and private label
159 distributors who are subject to the establishment registration requirements under the
160 Act. Hospitals, clinics, and public health agencies that only "maintain establishments
161 in conformance with any applicable laws regulating the practice of pharmacy or
162 medicine and that regularly engage in dispensing prescription drugs . . . upon
163 prescription of practitioners licensed by law to administer these drugs to patients
164 under their professional care" are exempt from the establishment registration
165 requirements (21 CFR 207.10(b)) and, by extension, are exempt from the bar code
166 rule (response to comment 2, 69 FR 9120 at 9123).
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168 **IMPLEMENTATION DATES**

169

170 **Q7: *How is the 2-year implementation date intended to work?***

171

172 A7: The 2-year implementation date is for drug products that received approval before
173 April 26, 2004. This 2-year period is intended to provide the industry sufficient time
174 to make the labeling changes necessary to comply with the rule by April 26, 2006.
175 Drugs approved on or after April 26, 2004, have 60 days from their approval date to
176 comply with the bar code rule.

177

178 **Q8: *Does the product expiration date have any bearing on the bar code requirements?***

179

180 A8. No. The expiration date of a product has no bearing on the bar code requirements.

181

182 **Q9: *If a drug was approved before the effective date of the final rule, but a supplement is***
183 ***still pending as of the effective date, what date is used to determine when the product***
184 ***needs to meet the bar code requirements?***

185

186 ***Should companies use the original new drug application (NDA) or biological license***
187 ***application (BLA) approval date (getting 2 years to comply), or does FDA intend to***
188 ***apply the supplement's approval date (triggering compliance within 60 days)?***

189

190 A9: The original application approval date is the applicable date for determining when a
191 product would need to meet the bar code requirements. As discussed in the preamble
192 to the final rule, we expect drugs approved before the effective date of this rule to
193 comply with the bar code requirements within 2 years of the effective date, i.e., on or
194 before April 26, 2006. Drugs approved on or after April 26, 2004, the effective date
195 of this rule, must comply within 60 days after the drug's approval date. (See response
196 to comment 71, 69 FR 9120 at 9147.) For circumstances in which a drug is approved
197 before April 26, 2004, and a supplement for a new potency or other change subject to
198 the approval of a supplement is approved after April 26, 2004, the application's
199 original approval date controls; therefore, we would expect the product subject to the
200 supplement to comply with the bar code requirements on or before April 26, 2006.

201

202

203 **QUALITY, APPEARANCE, AND PLACEMENT OF THE BAR CODE**

204

205 **Q10: *Can a firm use another automatic identification technology, such as a radio frequency***
206 ***identification chip or a two-dimensional symbology, instead of a linear bar code?***

207

208 A10: No. The final rule requires the use of a linear bar code to encode the NDC number on
209 most prescription drug products and certain OTC drug products. However, we will
210 not object if firms voluntarily encode lot number and expiration date information, and
211 we recognize that some firms might use other technologies to encode that additional
212 information (response to comment 35, 69 FR 9120 at 9134-9135).

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214 In addition, we stated in the preamble to the final rule that we will consider revising
215 the rule to accommodate new technologies and may begin examining other automatic
216 identification technologies by April 2006 (69 FR 9120 at 9138).

217
218 ***Q11: What should be used in lieu of an asterisk in an NDC?***

219
220 A11: Nothing should be put in place of the asterisk in an NDC number in a bar code.

221
222 Under 21 CFR 207.35(b)(2), the Agency uses the National Drug Code (NDC)
223 numbering system in assigning an NDC number. The number is a 10-character code
224 that uses only numerals.

225
226 The NDC number is divided into three segments. The first segment, the labeler code,
227 identifies the manufacturer or distributor and is four or five characters long. The
228 second segment, the product code, identifies the drug product and is three or four
229 characters long. The third segment, the package code, identifies the trade package
230 size and type and is one or two characters long. The 10-character NDC number can
231 be in the following three configurations of labeler code–product code–package code:
232 4–4–2, 5–4–1, or 5–3–2.

233
234 The asterisk is for FDA’s internal use only. For entries into our database, the asterisk
235 is a dummy character used to differentiate between the three different configurations.
236 A zero cannot be used in place of the asterisk because a zero is a real numeric
237 character in an NDC number. An NDC number that contains a non-numeric character
238 (an asterisk) reverts to a 10-numeric character code when used on the labeling of a
239 drug product or included in a bar code. For example, if the NDC number for a firm’s
240 product is in a 5–3–2 configuration, the Agency, potentially, assigns a dummy
241 asterisk as follows: 12345–*542–12. When a bar code is placed on the product, the
242 asterisk is dropped, and the number included in the bar code is 1234554212.

243
244 ***Q12: If a drug product has a bar code on the immediate container and the outer container is***
245 ***an overwrap through which the bar code is human-readable but not machine-readable,***
246 ***does the overwrap also have to contain the bar code if the drug product is administered***
247 ***without the overwrap?***

248
249 A12: Yes. The Agency intends for bar codes to be on the drug’s outside container or
250 wrapper as well as on the immediate container, unless the bar code is readily visible
251 ***and*** machine-readable through the outside container or wrapper (section II.E in the
252 preamble to the final rule, 69 FR 9120 at 9140). When the bar code is not easily
253 machine-readable through the overwrap, the overwrap should contain the bar code.
254 The fact that the overwrap is removed before administration does not change the
255 answer; to prevent medication errors, hospital personnel may need to scan the bar
256 code during the dispensing process before the overwrap is removed.

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Q13: *For a product packaged in blister cells divided by perforations that enable the cells to be separated, should there be one bar code for the entire package or does each cell need a bar code?*

A13: Assuming that each cell has a label, the bar code should go on each cell because the final rule requires that the bar code be on the drug's label. Furthermore, the bar code must remain intact under normal conditions of use; thus it should not be printed across the perforations of a blister pack (response to comment 43, 69 FR 9120 at 9140).

Q14: *Does FDA intend to issue guidance regarding bar code quality, such as size, symbol quality, symbol grade, reflectance?*

A14: No. We believe there are sufficient documents and standards issued by third parties to address such bar code quality and standard matters (response to comment 56, 69 FR 9120 at 9144).

MISCELLANEOUS

Q15: *Does FDA intend to buy bar code scanning equipment to promote bar code use in hospitals?*

A15: No. We have no intention to buy or distribute bar code equipment.