

Guidance for Industry

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

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

**Procedural
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39 **Guidance for Industry**
40 **Registration of Human Drug**
41 **Compounding Outsourcing Facilities**
42 **Under Section 503B of the FD&C Act**
43

44 *Additional copies are available from:*
45 *Office of Communications*
46 *Division of Drug Information, WO51, Room 2201*
47 *Center for Drug Evaluation and Research*
48 *Food and Drug Administration*
49 *10903 New Hampshire Ave., Silver Spring, MD 20993*
50 *Phone: 301-796-3400; Fax: 301-847-8714*
51 *druginfo@fda.hhs.gov*

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

53
54
55 *or*
56 *Office of Policy*
57 *Office of the Commissioner*
58 *Food and Drug Administration*
59 *10903 New Hampshire Ave.*
60 *Silver Spring, MD 20993*
61 *Phone: 301-796-4830*
62
63
64
65
66
67
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Guidance for Industry¹

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

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

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111. INTRODUCTION

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113 This guidance is intended for facilities planning to register or renew registration as human drug
114 compounding outsourcing facilities (outsourcing facilities). A compounder can elect to register
115 with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and
116 Cosmetic Act (FD&C Act) (21 U.S.C. 353b), as added by the Drug Quality and Security Act
117 (DQSA), Pub. Law No. 113-54 (November 27, 2013). This guidance describes the process for
118 electronic submission of establishment registration information for outsourcing facilities. In
119 certain rare cases, FDA may grant an entity a waiver from submitting registration information
120 electronically. This guidance also provides information on how to obtain such a waiver.

121

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

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129II. BACKGROUND

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131 A. Drug Quality and Security Act

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133 The DQSA adds new section 503B to the FD&C Act. Under section 503B(b) of the FD&C Act,
134 a compounder can elect to become an outsourcing facility and register with FDA. Each
135 outsourcing facility must report to FDA certain information about the drug products it
136 compounds. If the requirements in section 503B are met, drug products compounded in an
137 outsourcing facility can qualify for exemptions from the FDA approval requirements in section

¹ This guidance was prepared by the Office of Compliance, Center for Drug Evaluation and Research, at the Food
and Drug Administration.

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138505 of the FD&C Act (21 U.S.C.355) and the requirement to label products with adequate
 139directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)). Outsourcing
 140facilities will be inspected by FDA and must comply with other provisions of the FD&C Act,
 141such as current good manufacturing practice (CGMP) requirements.²

142

143After the initial registration, under section 503B(b) of the FD&C Act, a facility that elects to
 144register with FDA as an outsourcing facility must also do so annually for each year thereafter
 145that it wishes to remain an outsourcing facility, during the registration period between October 1
 146and December 31. Upon registration, the outsourcing facility must provide its name, place of
 147business, a unique facility identifier³, and a point of contact email address (section 503B(b)(1)
 148(A)(i)). The outsourcing facility must also indicate whether it intends to compound, within the
 149next calendar year, a drug that appears on FDA’s drug shortage list in effect under section 506E
 150of the FD&C Act (21 U.S.C. 356e) (section 503B(b)(1)(A)(ii)), and whether it compounds from
 151bulk drug substances, and, if so, whether it compounds sterile or nonsterile drugs from such bulk
 152drug substances.⁴

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154 **B. Scope of this Guidance**

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156This guidance document describes the process for registering as an outsourcing facility under
 157section 503B of the FD&C Act. Separate guidances provide instructions on payment of
 158registration fees and how outsourcing facilities should report to FDA the drug products they
 159compound.⁵ This guidance reflects FDA’s current thinking in light of existing data standards,
 160information technology, and information management resources. As these variables change over
 161time, FDA may revisit this guidance and the specifications described in section III of this
 162guidance.

163

18² FDA has issued a draft guidance on this topic (*Current Good Manufacturing Practice – Interim Guidance for
 19Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*. Once finalized, that
 20guidance will represent the Agency’s thinking on this topic.

21 FDA’s guidances are available on its guidance website. FDA updates guidances regularly. To make sure
 22 you have the most recent version of a guidance, visit the guidance website at
 23 <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

24³ See the guidance for industry *Specification of the Unique Facility Identifier (UFI) System for Drug Establishment
 25Registration*. Although this guidance is intended to address provisions set forth in section 510 of the FD&C Act,
 26FDA’s specification of the UFI system in this guidance also applies to facilities that register as outsourcing facilities
 27under section 503B of the FD&C Act.

28⁴ Although section 503B(b)(1)(A) does not specifically identify this information regarding bulk drug substances,
 29section 503B(b)(1)(B)(ii) requires FDA to publish this information on the Internet (see section III.B.3 below).
 30Therefore, FDA is requiring that this information be supplied as part of the registration submission.

31⁵ See guidances for industry *Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and
 32744K of the FD&C Act* and *Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities
 33Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

165III. REGISTERING WITH FDA AS AN OUTSOURCING FACILITY

167 A. Who Should Register

169A compounder can elect to register with FDA as an outsourcing facility. Each outsourcing
170facility at a separate geographic location or address must register separately. The outsourcing
171facility is not required to be a licensed pharmacy (although it may be a licensed pharmacy), and
172it may or may not obtain prescriptions for individual patients. An outsourcing facility engages in
173the compounding of sterile drugs. 503B(d)(4).

175 B. How to Register

177 1. Method for Outsourcing Facility Registration

179Facilities that elect to register with FDA as outsourcing facilities should submit registration
180information using the existing structured product labeling (SPL) format. For detailed
181instructions on how to submit information using SPL, outsourcing facilities should refer to
182section IV of the guidance for industry *Providing Regulatory Submissions in Electronic Format*
183— *Drug Establishment Registration and Drug Listing*. FDA also offers tools and information for
184creating and submitting SPL files. Additional information can be found at www.fda.gov/edrls.
186After initial registration, facilities must register annually, between October 1 and December 31
187of each year, to continue to be registered outsourcing facilities. FDA has created an SPL
188category of business operation for outsourcing facilities. All outsourcing facilities should submit
189establishment registration information using the business operation “Human Drug Compounding
190Outsourcing Facility.” If a facility chooses to register as an outsourcing facility, as required by
191section 503B(b)(1)(A) of the FD&C Act, it must submit the following information:

- 193 • Name of the facility
- 194 • Place of business
- 195 • Unique facility identifier
- 196 • Point of contact email address and phone number⁶
- 197 • An indication of whether the facility intends to compound products on FDA’s drug
198 shortage list
- 199 • An indication of whether the facility compounds from bulk drug substances, and if so,
200 whether it compounds sterile or nonsterile drugs from bulk drug substances⁷

202 2. Method for Outsourcing Facility De-Registration

204Facilities that have registered with FDA as outsourcing facilities can withdraw registration by
205submitting information to de-register using the SPL format. For detailed instructions on how to
206de-register, see section IV of the guidance for industry *Providing Regulatory Submissions in*
207*Electronic Format — Drug Establishment Registration and Drug Listing*.

38⁶ Section 503B(b)(1)(A) only requires registrants to include a point of contact email address. However, we
39recommend that registrants also supply a point of contact phone number.

40⁷ See footnote 4 above.

209 3. *Posting of Registration Information*

210

211 Section 503B(b)(1)(B)(ii) of the FD&C Act requires FDA to publish on the Internet a list of
 212 registered outsourcing facilities that includes the name of each registered outsourcing facility, the
 213 state in which it is located, whether the facility compounds from bulk drug substances, and
 214 whether such compounding from bulk drug substances is for sterile or nonsterile drugs.⁸ FDA
 215 will publish the required information including the date the facility registered as an outsourcing
 216 facility, as well as certain publicly disclosable information related to past FDA inspections and
 217 compliance actions. FDA intends to update the list of registered outsourcing facilities weekly.

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219 **C. Electronic Registration Waivers**

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221 Section 503B(b)(3) of the FD&C Act requires facilities to register by electronic means unless
 222 FDA grants a request for a waiver of this requirement “because use of electronic means is not
 223 reasonable for the person requesting the waiver.” FDA does not anticipate many instances in
 224 which electronic submission of registration information will not be reasonable for the person
 225 requesting the waiver because the information requested is minimal and the electronic system for
 226 submitting the information is an internet-based system accessible to all firms seeking to register.
 227 However, if you are granted a waiver, you will be instructed on how to submit the required
 228 registration information.

229

230 To apply for a waiver from the requirement to electronically submit drug establishment
 231 registration information, you should provide to the following address a written request with a
 232 complete explanation of why the use of electronic means is not reasonable for you:

233

234 Drug Registration and Listing System Team

235 U.S. Food and Drug Administration

236 10903 New Hampshire Avenue

237 Silver Spring, MD 20993-0002

238

239 or

240

241 Email: edrils@fda.hhs.gov

242

243 **D. Registration Fees**

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245 Under the DQSA, a facility is not considered registered until all registration fees owed by the
 246 facility have been paid (see section 744K(g)(3)(A) of the FD&C Act). Beginning in fiscal year
 247 (FY) 2015 (October 1, 2014 to September 30, 2015), facilities that elect to register with FDA as
 248 outsourcing facilities must pay an annual establishment fee (744K(a)(1)(A)). For detailed
 249 information on annual establishment fees for outsourcing facilities, refer to the guidance for

45⁸ The list is available at

46 <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm>.

47 Additional information concerning outsourcing facility registration is available at

48 <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm>.

250industry Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 251744K of the FD&C Act.

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