

---

# Guidance for Industry

## Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

### *DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact LT Lysette Deshields at [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov)

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

December 2013  
Procedural

---

# Guidance for Industry

## Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

*Additional copies are available from:*

*Office of Communications  
Division of Drug Information, WO51, Room 2201  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave., Silver Spring, MD 20993  
Phone: 301-796-3400; Fax: 301-847-8714  
druginfo@fda.hhs.gov*

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

or

*Office of Policy  
Office of the Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  
Phone: 301-796-4830*

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

**December 2013  
Procedural**

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

**TABLE OF CONTENTS**

<b>I.</b>	<b>INTRODUCTION.....</b>	<b>1</b>
<b>II.</b>	<b>BACKGROUND .....</b>	<b>1</b>
	<b>A. Drug Quality and Security Act.....</b>	<b>1</b>
	<b>B. Scope of This Guidance .....</b>	<b>2</b>
<b>III.</b>	<b>SUBMISSION OF PRODUCT REPORTING.....</b>	<b>2</b>
	<b>A. Who Should Report and What to Report.....</b>	<b>2</b>
	<b>B. When to Report.....</b>	<b>2</b>
	<b>C. How to Report.....</b>	<b>3</b>
<b>IV.</b>	<b>APPENDIX 1: SAMPLE INTERIM PRODUCT REPORTING SUBMISSION.....</b>	<b>4</b>

## Guidance for Industry<sup>1</sup>

# Interim Product Reporting for Human Drug Compounding Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act

This draft guidance 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 the approach 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

This guidance is intended for outsourcing facilities that compound human drugs (outsourcing facilities). Outsourcing facilities may elect to register with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b), as added by the Drug Quality and Security Act, (DQSA). If an outsourcing facility registers, it must report to FDA information about the drugs compounded at the outsourcing facility. This guidance focuses on electronic submission of drug reporting information.

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

## II. BACKGROUND

### A. Drug Quality and Security Act

The DQSA adds new section 503B to the FD&C Act. Under section 503B(b), a compounder may elect to become an outsourcing facility by registering with FDA. Upon initially registering as an outsourcing facility, and twice each year (once in June and once in December), an outsourcer that registers with FDA must submit to the Agency a report identifying the drugs compounded by the facility during the previous 6-month period. For each identified drug, the outsourcing facility must provide certain information listed in section 503B(b).

---

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

## *Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

42 An outsourcing facility can qualify for exemptions from the FDA approval requirements in  
43 section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with  
44 adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) by  
45 meeting the requirements described in the rest of section 503B. Outsourcing facilities will be  
46 inspected by FDA and must comply with other provisions of the FD&C Act, such as current  
47 good manufacturing practice (cGMP) requirements. Information about these requirements will  
48 be provided separately at a later date.

49

### 50 **B. Scope of This Guidance**

51

52 This guidance addresses the provisions in the DQSA regarding the drug reporting requirements  
53 for registered outsourcing facilities. A separate guidance provides instructions on how  
54 outsourcing facilities should register with FDA.<sup>2</sup> This guidance provides instructions for interim  
55 reporting until FDA can modify its electronic submission system to accept the electronic reports  
56 for drugs compounded by outsourcing facilities. When FDA has modified its current electronic  
57 system, we will issue a new outsourcing facility product reporting guidance describing the  
58 updated format for long-term use.

59

## 60 **III. SUBMISSION OF PRODUCT REPORTING**

61

### 62 **A. Who Should Report and What to Report**

63

64 Under section 503B of the FD&C Act, upon initial registration as an outsourcing facility under  
65 section 503B and twice each year (once in June and once in December), each registrant must  
66 submit a product report to FDA. This report must identify all drugs compounded by the  
67 outsourcing facility during the previous 6-month period and provide the following information  
68 for each drug:

69

- 70 • The active ingredient and strength of active ingredient per unit;
- 71 • The source of the active ingredient (bulk or finished drug);
- 72 • The National Drug Code (NDC) number of the source drug or bulk active ingredient, if  
73 available;
- 74 • The dosage form and route of administration;
- 75 • The package description;
- 76 • The number of individual units produced; and
- 77 • The NDC number of the final product, if assigned.

78

### 79 **B. When to Report**

80

---

<sup>2</sup> See Guidance for Industry: Registration for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act, available at:

<http://www.fda.gov/forindustry/industrynticesandguidancedocuments/default.htm>.

## *Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

81 Registered outsourcing facilities must report upon initial registration under section 503B of the  
82 FD&C Act, and twice each year (once in June and once in December). FDA encourages  
83 companies wishing to compound as outsourcing facilities to register with FDA immediately. If a  
84 facility registers before June 2, 2014, FDA does not intend to immediately enforce the  
85 requirement to report product information at the time of initial registration, as long as the facility  
86 submits its report within 2 months after the date of that initial registration.

87

### 88 **C. How to Report**

89

90 Section 503B(b)(3) of the FD&C Act requires outsourcing facilities to submit drug reporting  
91 information by electronic means unless FDA grants a request for a waiver of such requirement  
92 “because use of electronic means is not reasonable for the person requesting the waiver.”

93

94 Because FDA’s electronic submission systems are not currently equipped to handle electronic  
95 drug reporting from outsourcing facilities in Structured Product Labeling (SPL) format,  
96 outsourcing facilities should submit reporting data to the Agency in an Excel spreadsheet, via an  
97 email attachment. Product reporting can be submitted to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov). When the Agency  
98 has modified its electronic submission system to allow outsourcers to submit information  
99 electronically through an SPL file, FDA intends to issue a draft guidance describing the updated  
100 format for long-term use. When such guidance is in final form, it will specify the form of  
101 reporting that outsourcing facilities are to follow. A sample Excel spreadsheet for an interim  
102 outsourcing facility product submission can be found at Appendix 1.

103

104 FDA does not anticipate many instances in which electronic submission of reporting information  
105 will not be reasonable for the outsourcing facility requesting a waiver. However, if a waiver is  
106 granted, the Agency will also give instructions on how to submit the required reporting  
107 information. To apply for a waiver from the requirement to electronically submit drug reporting  
108 information, please provide a written request with a complete explanation of why the use of  
109 electronic means is not reasonable to:

110

111 Drug Registration and Listing System Team

112 U.S. Food and Drug Administration

113 10903 New Hampshire Avenue

114 Silver Spring, MD 20993

115

116 or

117

118 Email: [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

119

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

120  
121

**APPENDIX 1: SAMPLE INTERIM PRODUCT REPORTING SUBMISSION**

Interim Product Reporting for Human Drug Compounding Outsourcing Facilities							
Outsourcing Facility Information							
Facility Name	UF	Contact Name	Contact Phone	Contact Email			
Product Information							
Product Name	Product NDC	Active Ingredient Name	Strength of Active Ingredient/ Unit	Dosage Form	Route of Administration	Package Description	# of Units
Source NDC							
NDC	Bulk or Finished						

122