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# Guidance for Industry Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act

## *DRAFT GUIDANCE*

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For questions regarding this draft document contact FDA, Center for Drug Evaluation and Research, Office of Business Informatics at [CDER-OBI-ACA6004@fda.hhs.gov](mailto:CDER-OBI-ACA6004@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)**

**July 2014  
Electronic Submissions  
Revised Draft**

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# Guidance for Industry Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act

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**U.S. Department of Health and Human Services  
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**Guidance for Industry<sup>1</sup>**  
**Reporting Drug Sample Information**  
**Under Section 6004 of the Affordable Care Act**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 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 document is intended to assist persons reporting drug sample distribution information<sup>2</sup> to FDA under section 6004 of the Patient Protection and Affordable Care Act (ACA). The guidance explains, among other things:

- The statutory requirement to submit drug sample distribution information
- Definitions relevant to drug sample distribution information submissions
- Who submits drug sample information
- What information is to be submitted
- How to submit the information
- When to submit the information
- FDA's compliance policies related to drug distribution information submissions

This draft revises the April 3, 2012, draft guidance for industry entitled *Compliance Policy on Reporting Drug Sample Distribution Information*. This draft revision updates the information in the April 2012 guidance to better assist persons using the Gateway to submit drug sample information under ACA section 6004 and to advise industry of an updated compliance policy. The revised draft guidance replaces the April 3, 2012, draft guidance.

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

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<sup>1</sup> This guidance has been prepared by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

<sup>2</sup> For purposes of this guidance the term *drug sample* means a unit of a drug, subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which is not intended to be sold and is intended to promote the sale of the drug.

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cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## II. BACKGROUND

On March 23, 2010, the ACA was signed into law. Among its many provisions, section 6004 amended the Social Security Act by adding section 1128H (42 U.S.C. 1320a-7i). This new section requires the submission of certain drug sample information to FDA not later than April 1 of each year, beginning April 1, 2012.

In particular, section 6004 requires manufacturers and authorized distributors of record (ADRs) of “applicable drugs” to annually report the identity and quantity of drug samples that were requested and distributed under section 503(d)(2) and (d)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>3</sup> This information must be aggregated by: (1) the name, address, professional designation, and signature of the practitioner making the drug sample request or of any individual who makes or signs for the request on behalf of the practitioner; and (2) any other category of information determined appropriate by the Secretary of the U.S. Department of Health and Human Services (Secretary).<sup>4</sup> The Secretary has delegated to FDA the authority to issue guidance identifying the information to be submitted under section 6004, and to oversee and arrange for the collection of such information.

Section 6004 is not part of the Prescription Drug Marketing Act (PDMA) but must be read together with that Act. Two of the terms used in section 6004 are defined by reference to the PDMA. In addition, the PDMA and its implementing regulations<sup>5</sup> require the collection and maintenance of information that must be submitted under section 6004. For example, 21 CFR 203.38(b) requires that a manufacturer or ADR *maintain* records of drug sample distribution for all samples distributed under section 503(d)(2) or 503(d)(3) of the FD&C Act that are sufficient to permit tracking of sample units to the point of the licensed practitioner. Under section 6004, manufacturers and ADRs must now *submit* much of the same information, aggregated as specified, to FDA.

On April 3, 2012, FDA issued a draft guidance, entitled *Guidance for Industry -- Compliance Policy on Reporting Drug Sample Distribution Information Under the Affordable Care Act*, concerning section 6004. In that guidance, FDA explained the availability of the Electronic Submissions Gateway (the Gateway) for submission of drug sample information required by section 6004, FDA’s temporary compliance policy with regard to those submissions, and FDA’s intent to issue subsequent guidance. FDA is now issuing this guidance to provide information to assist persons submitting drug sample information under section 6004, and to advise industry of a new compliance policy. For technical instruction on using the Gateway system to report drug

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<sup>3</sup> See 21 U.S.C. 353(d)(2) and (d)(3).

<sup>4</sup> See 42 U.S.C. 1320a-7i(a).

<sup>5</sup> See 21 CFR part 203 subpart D.

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sample distribution information, please refer to *Affordable Care Act (ACA) 6004 – ACA Industry Submission Specifications User Guide*.<sup>6</sup>

### III. DISCUSSION

#### A. What Definitions Apply?

As noted above, the reporting requirement in section 6004 of the ACA (adding 1128H to the Social Security Act) applies to distributions of certain drugs under 503(d)(2) and (d)(3) of the FD&C Act. FDA intends to use the following definitions in implementing the requirements of section 6004:

1. **Applicable drug:** An applicable drug is a drug that is subject to section 503(b) of the FD&C Act (21 U.S.C. 353(b)) and for which payment is available under title XVIII of the Social Security Act (SSA) or a State plan under title XIX or XXI of the SSA (or a waiver of such a plan).<sup>7</sup>
2. **Authorized distributor of record (ADR):** “[T]hose distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products.”<sup>8</sup> An entity that is an ADR under section 503(d) of the FD&C Act is also an ADR under section 1128H of the SSA.<sup>9,10</sup>
3. **Ongoing relationship:** An association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer’s products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer’s entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.<sup>11</sup> FDA uses this definition in determining whether an entity is an ADR making distributions under 503(d)(2) or (3).
4. **Distribute:** To sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term does not include (1) delivering or offering to deliver a drug by a common

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<sup>6</sup> <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM297610.pdf>.

<sup>7</sup> SSA section 1128H(b)(1) (42 U.S.C. 1320a-7i(b)(1)).

<sup>8</sup> Effective January 1, 2015, section 583(b) and (c) of the Drug Supply Chain Security Act, (part of the Drug Quality and Security Act (DQSA), signed into law on November 27, 2013) the definition of ADR was moved to section 503(d)(4) of the FD&C Act.

<sup>9</sup> SSA section 1128H(b)(2) (42 U.S.C. 1320a-7i(b)(2)), incorporating the meaning of this term codified in section 503(e)(3) of the FD&C Act (21 U.S.C. 353(e)(3)).

<sup>10</sup> For more information about the definition of *ADR* and ongoing relationship for purposes of section 503(d) of the FD&C Act, see <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM134399.pdf>.

<sup>11</sup> See 21 CFR 203.3(u).

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carrier in the usual course of business as a common carrier; or (2) providing a drug sample to a patient by a practitioner licensed to provide the drug, or by a health care professional acting at the direction and under the supervision of such a practitioner; or by the pharmacy of a hospital or another health care entity acting at the direction of a licensed practitioner that received a sample in accordance with the FD&C Act and related regulations.<sup>12</sup>

5. **Drug sample:** A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.<sup>13</sup>
6. **Manufacturer:** “[T]he person who performs all of the following operations that are required to produce the product: (1) Mixing, (2) granulating, (3) milling, (4) molding, (5) lyophilizing, (6) tableting, (7) encapsulating, (8) coating, (9) sterilizing, and (10) filling sterile, aerosol, or gaseous drugs into dispensing containers.”<sup>14</sup>

**B. Who Submits Drug Sample Information?**

The requirement to submit drug sample information under section 6004 of the ACA applies to each manufacturer and ADR of an applicable drug that makes distributions under subsection (d)(2) or (d)(3) of section 503 of the FD&C Act. In general, this means that both manufacturers and ADRs of applicable drugs should submit drug sample information to FDA.

We recognize that there may be instances when a manufacturer and ADR both have records regarding the same drug sample request or distribution. In such cases, only one of the two entities should submit the required drug sample information to FDA. For example, when a manufacturer provides an applicable drug sample to an ADR, which in turn distributes the drug sample to a physician, the distribution to the physician should be reported only once — by either the manufacturer *or* the ADR. Given that manufacturers and their ADRs are required to have written documentation of their relationship (21 CFR 203.3(b),(u)), we recommend that ADR agreements specify who is responsible for reporting the required drug sample information to FDA.

FDA also recognizes that there may be instances when requests for samples are transmitted to a manufacturer through an ADR, or when multiple ADRs are used to fulfill a single sample request received by a manufacturer. FDA expects manufacturers to ensure that the submissions for such drug sample requests and distributions are complete and non-duplicative. FDA believes that manufacturers are best positioned to determine who will do the reporting for their drug sample requests and distributions. FDA will not object if a third party is contracted by the manufacturer to provide the report to FDA, provided the contractor clearly identifies the manufacturer for

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<sup>12</sup> See 21 CFR 203.3(h).

<sup>13</sup> See 21 CFR 203.3(i).

<sup>14</sup> See 21 CFR 201.1(b). See also SSA section 1128H(b)(3) (42 U.S.C. 1320a-7i(b)(3)), incorporating the meaning given to the term “manufacturer” for purposes of section 503(d) FD&C Act.

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whom it is reporting. In each such case, the person or firm submitting a report should identify the manufacturer for whom the report is being made.

**C. How Should Drug Sample Information Be Reported?**

FDA strongly encourages use of the Electronic Submissions Gateway (Gateway) for the submission of drug sample data required by section 6004 of the ACA. The Gateway became available for drug sample reporting under section 6004 in March 2012, and FDA intends to continue the use of the Gateway for this purpose. For information about the Gateway, which is also used for a number of other submissions to FDA, see <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>. This website provides useful information, including how to setup a Gateway account.

The Gateway accepts submissions made in XML format. For technical specifications, contact information, and other helpful information for creating section 6004 submissions, see <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm>. Among other things, this page contains a link for downloading the XML schema for a submission and an XML example, as well as a user guide and a document that provides answers to frequently asked questions.

For questions about the Gateway, please contact [esgreg@gnsi.com](mailto:esgreg@gnsi.com). For all other questions about making a section 6004 submission, please contact [cdcr-obi-aca6004@fda.hhs.gov](mailto:cdcr-obi-aca6004@fda.hhs.gov).

**D. What Drug Sample Information Should Be Included in a Submission?**

Under section 6004 of the ACA, manufacturers and ADRs of applicable drugs must submit the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed, aggregated by the name, address, professional designation, signature of the practitioner making the request, and signature of the practitioner or the practitioner's designee receiving the distributed drug samples. As noted above, we request that the required information be submitted only once; the manufacturer and its ADRs should determine who is best suited to make these submissions.

We read section 6004 as requiring that manufacturers and ADRs provide information about the identity and quantity of all drug sample requests and distributions made under sections 503(d)(2) and 503(d)(3) of the FD&C Act. Below, we discuss our interpretation of certain terms in section 6004, the aggregation of drug sample reports, and the period to be covered by each report.

**1. Background – Requirements of the PDMA and Section 6004 of the ACA**

In general, the information reported to FDA under section 6004 should be based on information that a manufacturers or ADR collected under the PDMA. As set forth in the PDMA regulations, drug samples may be requested only by practitioners licensed in their state to prescribe the requested drugs.<sup>15</sup> A written request containing the practitioner's

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<sup>15</sup> See 21 CFR 203.30 and 203.31.



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name, address, professional designation, identity of the drug sample requested, quantity of drug sample requested, and signature of the practitioner making the request must be received by the manufacturer or ADR for each drug sample distribution.<sup>16</sup> Drug samples may be delivered to a practitioner's office or practice, an affiliated hospital pharmacy, or another place where someone other than the requesting practitioner may sign for receipt of the drug samples. If someone other than the requesting practitioner receives a sample, that person must be designated by the practitioner as an authorized recipient of the drug sample and sign for the sample on the practitioner's behalf. These signatures should be collected to enable compliance with the PDMA and should provide the information needed to compile the reports required by section 6004.

2. Identity of drug samples requested or distributed

When reporting drug sample information to FDA, the information provided should be sufficient for the Agency to identify each unique drug product sample that was requested or distributed. The drug sample information submitted via the Gateway must include the following data elements: trade name, strength, dosage of the samples, and sample package size (which includes the units/#per unit dosage).

3. Aggregation of drug sample information

FDA interprets the aggregation requirements in section 6004 to require that the quantity of drug samples requested and distributed be reported, with respect to each drug product,

- for each person who makes a drug sample request, and
- for each person who signs at the time of a drug sample distribution.

Thus, if a practitioner requested 300 samples of drug X and signed for 300 samples of drug X, both quantities would be reported for that practitioner. Alternatively, if a practitioner requested 300 samples of drug Y and designated a pharmacist to sign for 300 samples of drug Y, these quantities would be reported separately for the practitioner and pharmacist.

In addition, we interpret section 6004 to require that an address be provided for each requester and designee. Section 6004 requires aggregation by the address of the practitioner making the request and the address of the individual who signs for delivery of the requested samples (which may be the same as or different from the practitioner's address). The elements permitted in the Gateway for a standard address consist of a street number, street name, suite or room number, the U.S. city name, a two-letter abbreviation of the U.S. state, and a zip code in the format of 12345-6789.

We also interpret section 6004's requirement that drug sample information be aggregated by signature to mean that the information be aggregated by person for each person who requests and, at the time of delivery, signs for a drug sample under section 503(d)(2) or (d)(3). Accordingly, a section 6004 submission should aggregate drug sample information by (1) the

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<sup>16</sup> See 21 CFR 203.30(b).

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name of, and professional designation (title) for, each practitioner who made a request, and (2) each designated person, if other than the requesting practitioner, who received the drug samples.

FDA does not believe that the actual, individual signatures must be submitted to comply with the provision in section 6004 that requires “aggregation” of drug sample information by signature. It would be impractical for manufacturers or ADRs to submit, and for FDA to receive, such voluminous records. Thus, the Gateway includes checkboxes to indicate whether the signature of the medical practitioner who actually signed a request for samples and the person who signed for the delivered samples (either the requesting practitioner or the practitioner’s designee) are on file with the manufacturer or ADR. The example below illustrates how the Gateway should be used to report signature information for drug sample requests and distributions.

**Example:** Dr. Jones requests 500 samples of drug product X. The manufacturer distributes 250 samples to Dr. Jones at her clinic, and at Dr. Jones’ request, the remaining 250 are delivered to Dr. Jones’ designee, Mr. Smith, at a different address. The manufacturer determines that it has appropriate signatures on file for the drug sample request and for the samples distributed to Dr. Jones and Mr. Smith. The manufacturer should use the Gateway to report that Dr. Jones requested 500 samples of drug product X, that Dr. Jones received 250 of those samples, and that Mr. Smith received the remaining 250 samples. The addresses for both Dr. Jones and Mr. Smith should be provided, and the manufacturer should affirm that it maintains the signature information for Dr. Jones and Mr. Smith by checking the appropriate box in the Gateway submission window.

The ACA 6004 XML schema and a sample demonstrating aggregation reporting may be found in a link (“ACA 6004 XML Schema and Sample”) available from FDA’s Affordable Care Act (ACA 6004) webpage at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm>.

4. Period covered by each report

Section 6004 requires reports to be submitted not later than April 1 of each year with respect to the previous year. FDA interprets this requirement to mean that a report is required each year, submitted no later than April 1, for the distributions and requests that occurred during the previous calendar year. For example, manufacturers and ADRs must report, not later than April 1, 2014, on distributions and requests that occurred between January 1, 2013, and December 31, 2013.

Requests and distributions are to be reported for the year in which they occurred. FDA recognizes that, as a consequence, the number of requests and the number of deliveries may not be the same for a given reporting period. For example, if a practitioner requests 100 samples of drug X and the manufacturer fulfills only half of the request before the year ends, a report for that year would show 100 samples requested and 50 distributed. If the manufacturer filled the rest of the request in the following year, the manufacturer would report the distribution of 50

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samples to that physician, along with any other distributions made to that physician (or the physician's designee) during the calendar year in which the distributions were made.

**E. FDA's Compliance Policies**

Section 6004 of the ACA required the submission of information concerning drug sample distribution to FDA beginning April 1, 2012. On April 3, 2012, FDA issued a draft guidance explaining that, although the Gateway had become available for submissions, FDA intended to use enforcement discretion until at least October 1, 2012, for manufacturers and ADRs who had not submitted information under those reporting provisions. FDA further explained that it intended to notify relevant manufacturers and ADRs before lifting this exercise of discretion. FDA based this decision in large part on the newness of the requirement and the unavailability of the Gateway for submissions before late March 2012.

Before October 1, 2012, FDA announced on its website<sup>17</sup> that it was not revising its compliance policy with regard to section 6004 submissions, and that FDA expected to issue further guidance regarding its compliance policy, including the timing of FDA enforcement decisions, in 2013. This guidance reflects FDA's position with regard to its enforcement of the requirements in section 6004. FDA expects manufacturers and ADRs to comply with section 6004 according to the policies set forth in this guidance, beginning with the submission of data for 2014 due no later than April 1, 2015.

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<sup>17</sup> <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm>