Guidance for Industry

Compliance Policy on Reporting Drug Sample Distribution Information

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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For questions regarding this draft document contact (CDER) Donovan F. Duggan II, 301-796-0584 or (CBER) Office of Communication, Outreach, and Development at 800-835-4709 or 301-827-1800.

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)

April 2012
Electronic Submissions

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Contains Nonbinding Recommendations

Draft – Not for Implementation

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Section 6004 of the Patient Protection and Affordable Care Act requires that manufacturers and authorized distributors of record (ADRs) submit certain drug sample information to the Secretary of the U.S. Department of Health and Human Services not later than April 1 of each year, beginning April 1, 2012 (see 42 U.S.C. 1320a-7i). The Secretary has delegated authority to the Food and Drug Administration (FDA or Agency) to, among other things, issue guidance to identify the information to be submitted under section 6004 and to oversee and make arrangements for the collection of such information. The Agency is working to implement section 6004, and this guidance provides information on our implementation efforts. The guidance also announces that the Food and Drug Administration (FDA or Agency) does not intend to object until at least October 1, 2012, if manufacturers and authorized distributors of record (ADRs) do not submit information under section 6004, and that we intend to provide notice before revising our exercise of discretion with respect to compliance.

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.

[1] This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

II. BACKGROUND

On March 23, 2010, the Affordable Care Act 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 ADRs who distribute prescription drug samples under section 503(d)(2) or (d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)(2) and (d)(3)) to submit to the Secretary the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed. This required sample information must be provided to the Secretary aggregated by: (a) the name, address, professional designation, and signature of the practitioner making the request or of any individual who makes or signs for the request on behalf of the practitioner; and (b) by any other category of information determined appropriate by the Secretary (see 42 U.S.C. 1320a-7i(a)). The Secretary has delegated authority to the Food and Drug Administration (FDA or Agency) to, among other things, issue guidance to identify the information to be submitted under section 6004 and to oversee and make arrangements for the collection of such information.

FDA plans to use the Electronic Submissions Gateway ("the Gateway") that is used for a number of other submissions to FDA for the submission of drug sample data required by section 6004 (for information about the Gateway, see http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm). Updates to the Gateway and the associated database to allow the submission of information under section 6004 are in development, and we expect them to be complete by April 1, 2012.

III. AGENCY COMPLIANCE POLICY

FDA recognizes that the requirement to submit information to the Agency under section 6004 is new to industry and believes that providing additional time to manufacturers and ADRs is likely to improve the quality of submissions under this section and facilitate use of the Gateway as the method of providing required information to the Agency. Additional time also will allow FDA to ensure that the Gateway and database are able to accommodate the volume of submissions that we expect when industry is in full compliance with section 6004. Accordingly, FDA does not intend to object until at least October 1, 2012 if manufacturers and ADRs do not submit information under section 6004, and we intend to provide notice before revising our exercise of discretion with respect to compliance.

As of April 1, 2012, a manufacturer or ADR seeking to comply with section 6004 while this policy is in place may use the Gateway. The Gateway, along with FDA contact information regarding the Gateway, is available at the following Web address: http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm. Should you have other questions regarding a section 6004 submission, you may consult the Agency's Web page at the following Web address for contact information: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm.