EXHIBIT B

Guidance for Industry

180-Day Exclusivity: Questions and Answers

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Harry Schwirck 301-796-4271; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm.3128, Silver Spring, MD 20993-0002, 800-835-4709 or 240-402-8010.

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January 2017
Generic Drugs

Guidance for Industry

180-Day Exclusivity: Questions and Answers

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Contains Nonbinding Recommendations

Draft — Not for Implementation

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Guidance for Industry
180-Day Exclusivity: Questions and Answers[1]

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I. INTRODUCTION

This guidance is intended to address questions that have been raised about the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that relate to generic drug exclusivity, which commonly is known as *180-day exclusivity* for generic drug products. As a general matter, the Food and Drug Administration (FDA or the Agency) has implemented these statutory provisions within the context of application-specific decisions. Some FDA decisions have been made publicly available (e.g., in FDA citizen petition responses and documents released in litigation). In addition, in certain circumstances where a novel issue of interpretation was raised by a particular factual scenario regarding forfeiture of 180-day exclusivity, FDA has opened a public docket or otherwise sought comment from affected parties in advance of taking an action. Also, in certain instances, applicants have submitted correspondence to their abbreviated new drug applications (ANDAs) regarding 180-day exclusivity, which FDA has considered in making decisions. FDA believes that a guidance for industry that provides answers to commonly asked questions about 180-day exclusivity would enhance transparency and facilitate the development, approval, and timely marketing of generic drug products. FDA intends to update this guidance to include additional questions and answers (Q&As) as appropriate.

In general, FDA's guidance documents 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

The *Drug Price Competition and Patent Term Restoration Act of 1984* (the Hatch-Waxman Amendments)[2] to the FD&C Act established the ANDA approval pathway for generic drugs.[3] In

[1] This guidance has been prepared by the Office of Generic Drug Policy in the Center for Drug Evaluation and Research at the Food and Drug Administration.
[2] Public Law 98-417.

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