Draft Guidance for Industry on Bioequivalence Recommendations for Paliperidone Palmitate Extended-Release Injectable Suspension; Availability

I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at http://www.fda.gov/Drugs/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for paliperidone palmitate extended-release injectable suspension.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 27, 2013.
Leslie Kux,
Assistant Commissioner for Policy.

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