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From: U.S. Food and Drug Administration <fda@info.fda.gov>
Sent: Tuesday, June 18, 2019 4:25 PM
To: Kurt R. Karst
Subject: FDA to provide new data regarding eligibility for 180-day exclusivity – Drug Information Update

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FDA to provide new data regarding eligibility for 180-day exclusivity

As part of its ongoing efforts to provide transparency and assist generic drug applicants with planning regarding their applications, the Food and Drug Administration (FDA or the Agency) regularly publishes a list – the Paragraph IV Patent Certifications list – that contains information relevant to eligibility for 180-day exclusivity for generic drug products under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, this list pertains to drug products for which one or more substantially complete abbreviated new drug application (ANDA) containing a "paragraph IV (PIV) patent certification" has been submitted to FDA.

Since March 2, 2004, this list has included the name of the drug product, dosage form, strength(s), reference listed drug (RLD) new drug application (NDA) number, and the date on which the first substantially complete application containing a paragraph IV certification was submitted to the Agency.

Under the Agency's Drug Competition Action Plan (DCAP), FDA committed to enhancing efficiency of the development and approval of ANDAs, with the ultimate goal of more approvals, thereby helping to increase access to high-quality, lower cost generic drugs. FDA believes that additional information regarding 180-day exclusivity for specific drug products should support this DCAP goal by providing greater clarity to ANDA applicants on information related to 180-day exclusivity and may help generic drug applicants make business decisions. Accordingly, on a prospective basis beginning June 18, 2019, the Agency will now also publish additional data in the existing Paragraph IV Patent Certifications list, including the number of potential first applicants, the 180-day decision status, the date of first "first applicant" approval, the date of first commercial marketing, and the expiration date of last

qualifying patent. An explanation of the new fields has also been added to the Paragraph IV Patent Certifications web page.

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