

OVERVIEW

So, you work at a branded drug company and have just been handed a Paragraph IV letter. What do you do? If you work at a big company that has received dozens in the past, you probably already know what to do, but what if this is your first rodeo? Here are some tips that every recipient should know.

First, document retention. If you haven't already put in place a retention policy related to the drug, there is little doubt that on receipt of the Paragraph IV, you better do so. The Paragraph IV is the first step in the litigation process and Congress designed it to give a chance to branded drug companies to litigate their claims before generic launch. But with that opportunity, comes the responsibilities required in all litigations. Your favorite and mine: document retention. You can be assured that if documents are lost or discarded after the date the Paragraph IV certification is received, the generic challenger will assert that this is a violation of the duty to retain documents. While certainly there is some room for argument about this, the safest course is simply put it in place once you receive the Paragraph IV notice.