

Recent FDA Decisions Regarding Forfeiture of 180-Day Exclusivity

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ANDA Certification

- (I) the patent information has not been filed;
- (II) the patent has expired;
- (III) the patent will expire; or
- (IV) the patent is *invalid or will not be infringed* by the manufacture, use, or sale of the new drug for which the application is submitted

180-Day Exclusivity

- A first applicant to submit a ¶ IV:
 - 180-day exclusivity upon commercial marketing to compete with the brand

Medicare Modernization Act (MMA): 21 U.S.C. § 505(j)(5)(B)(iv) & (D);
21 U.S.C. § 355(j)(5)(B)(iv)(I)

- 180-day exclusivity period does not:
 - Outlast expiration of the patent (certification changes from ¶ IV to ¶ II)
 - Block other ANDAs filed pursuant to a non-¶ IV
 - Bar non-patented use accompanied by a § viii statement that the patent does not claim a use for which the applicant is seeking approval

21 U.S.C. § 355(j)(2)(A)(viii)

Forfeiture Provisions

An applicant forfeits its 180-day exclusivity if it fails to market by the later of:

(aa) the earlier of the date that is

(AA) **75 days** after the date of the approval of the application of the first applicant, or

(BB) **30 months** after the date of submission of the application of the first applicant; OR

(bb) **75 days** after the date as of which at least 1 of the following has occurred (**litigation safe harbor**):

(AA) final decision (appellate court) that the patent is invalid or not infringed

(BB) court ordered settlement order or consent decree that includes a finding that the patent is invalid or not infringed

(CC) patentee delists the patent

21 U.S.C. § 355(j)(5)(D)(i)(I)

Other Forfeiture Provisions

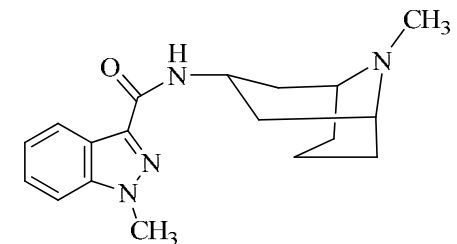
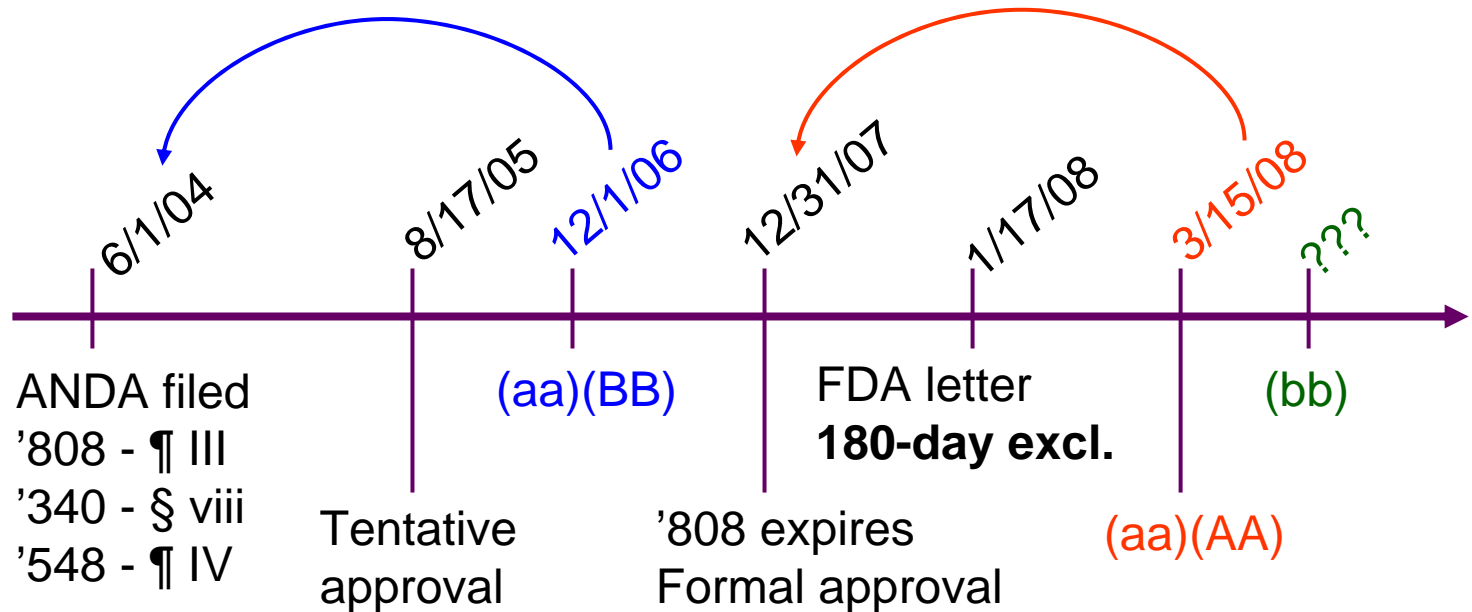
- Failure to obtain tentative approval
 - within **30 months** after the date the application is filed, unless the failure is caused by a change in requirements for approval

21 U.S.C. § 505(j)(5)(D)(i)(IV)

- Withdrawal of application
- Amendment of ANDA to non-¶ IV
- Antitrust violation
- Patent expires

21 U.S.C. § 505(j)(5)(D)(i)(II)-(VI)

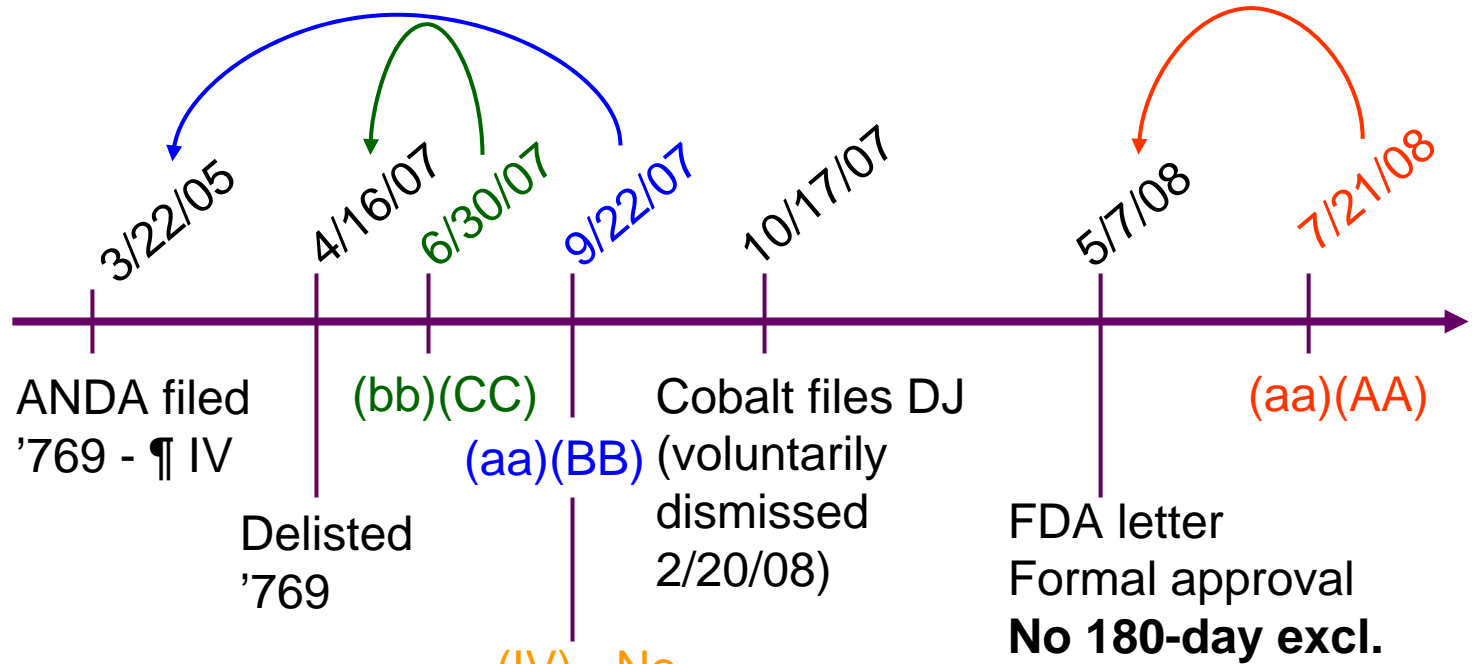
Teva: Granisetron



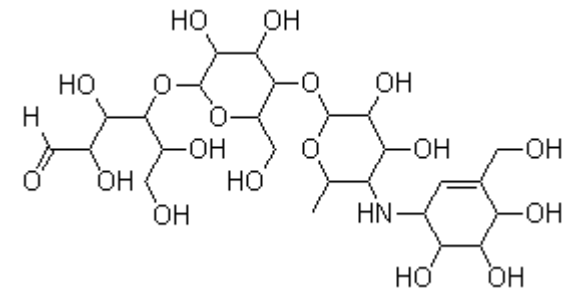
Teva: Granisetron

- What happens when no “later” event under (bb) has occurred at the time the FDA makes its exclusivity determination and the applicant has failed to market under (aa)?
 - “We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but - as in this case - none of the events in subpart (bb) has occurred.”
 - FDA explained that this is not a situation in which it would be impossible for a later event to occur
- Teva did not forfeit its exclusivity

Cobalt: Acarbose



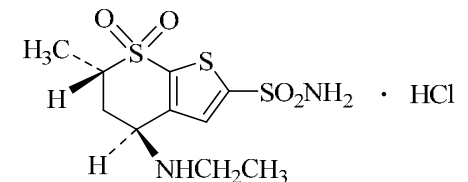
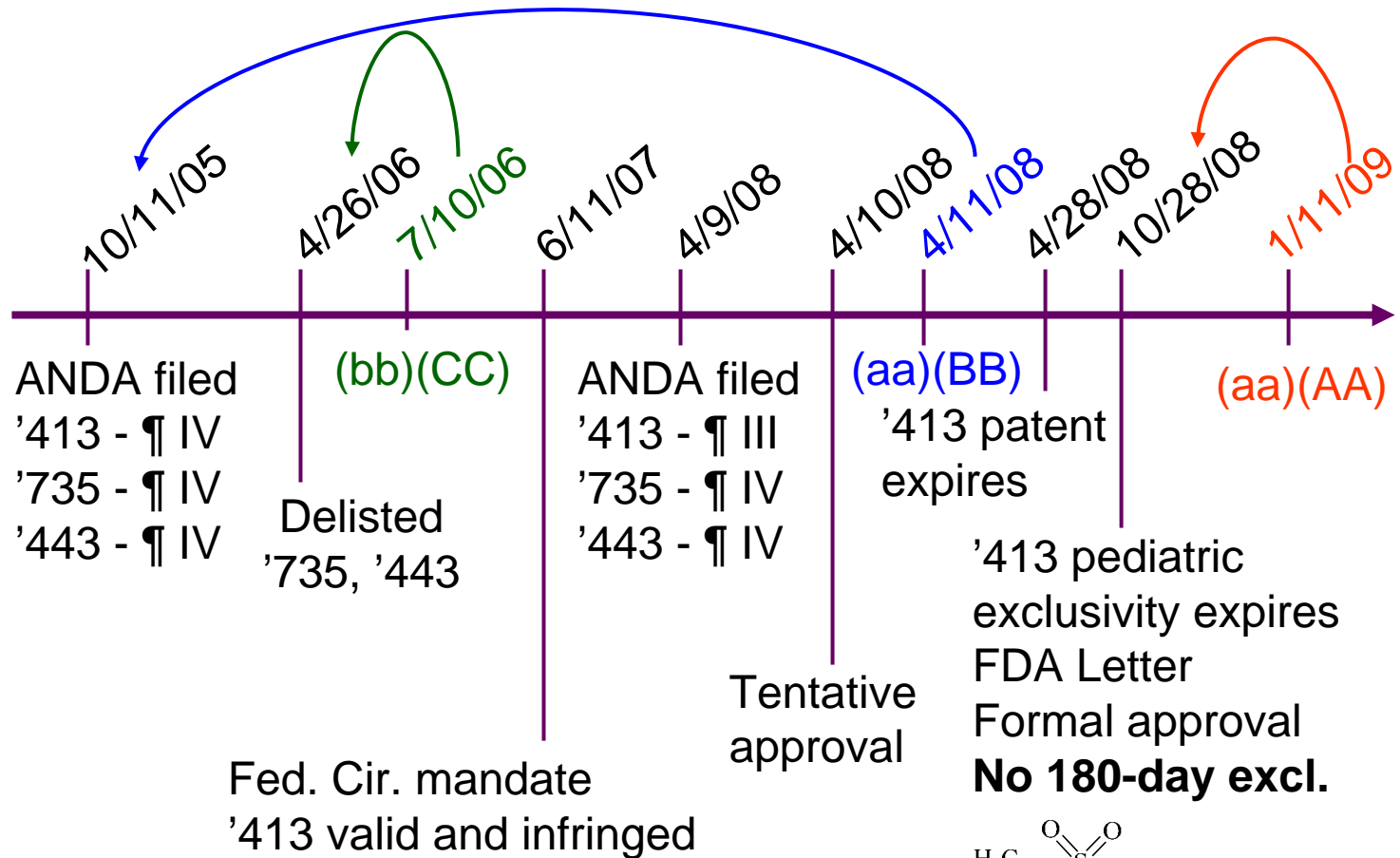
(IV) - No tentative approval yet



Cobalt: Acarbose

- Cobalt forfeited its exclusivity for failure to market
 - Cobalt failed to market by 9/22/07, the (aa)(BB) date - this is the earlier of the (aa)(AA) and (aa)(BB) date and the later of the (aa) and (bb) date
 - The 30 month periods in § 505(j)(5)(D)(I) & (IV) do not begin to run with receipt of the notice letter, but with date ANDA is submitted or filed
- Cobalt did not forfeit its exclusivity for failure to obtain tentative approval
 - Cobalt did not have tentative approval within 30 months of filing, but it was caused in part by the FDA's change in review of the bioequivalence requirements

Hi-Tech: Dorzolamide

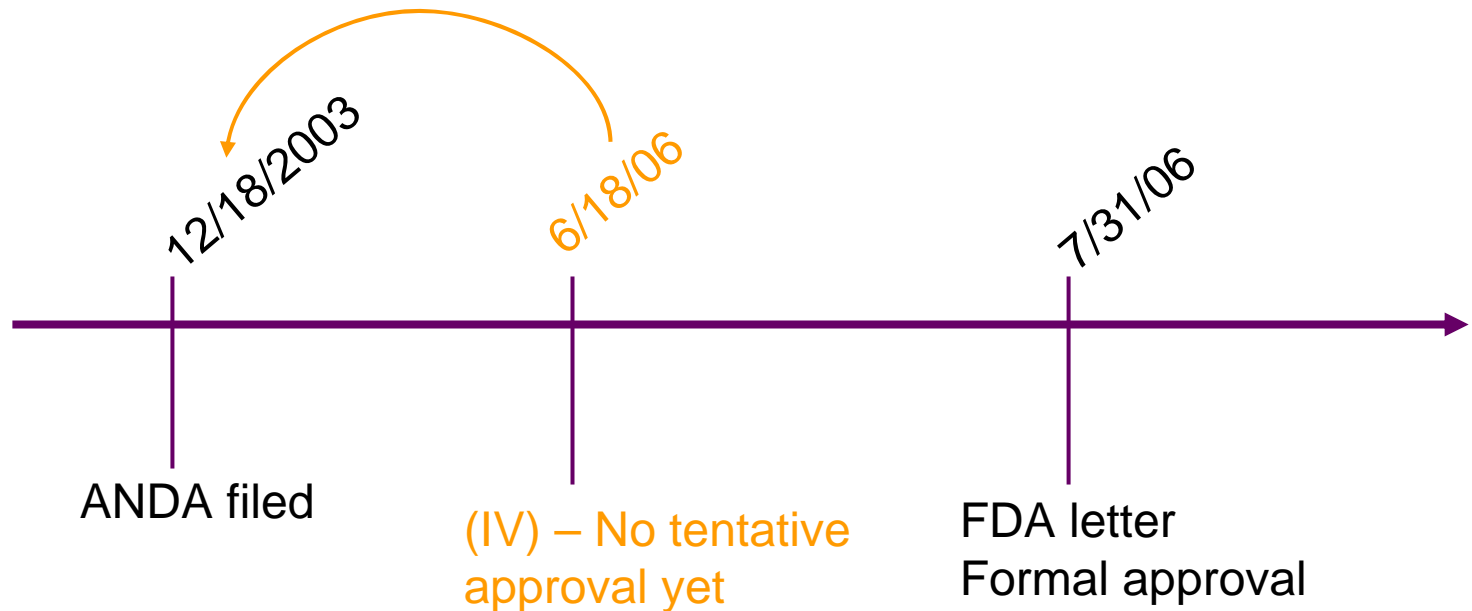


Hi-Tech: Dorzolamide

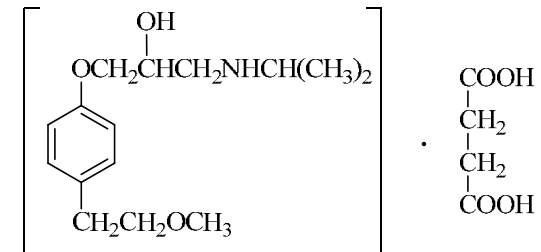
- Hi-Tech forfeited eligibility
 - Hi-Tech failed to lawfully maintain a ¶ IV for the '413 patent because it lost its patent litigation
 - Hi-Tech lawfully maintained ¶ IV for the '443 and '735 patents, but it failed to market by 4/11/08, the (aa)(BB) date - this is the earlier of the (aa)(AA) and (aa)(BB) date and the later of the (aa) and (bb) date
- Forfeiture under section 505(j)(5)(D)(i)(I) does not require the ANDA applicant be at fault
 - It is irrelevant that Hi-Tech was not able to market because of Merck's pediatric exclusivity

If a tree falls in the forest...

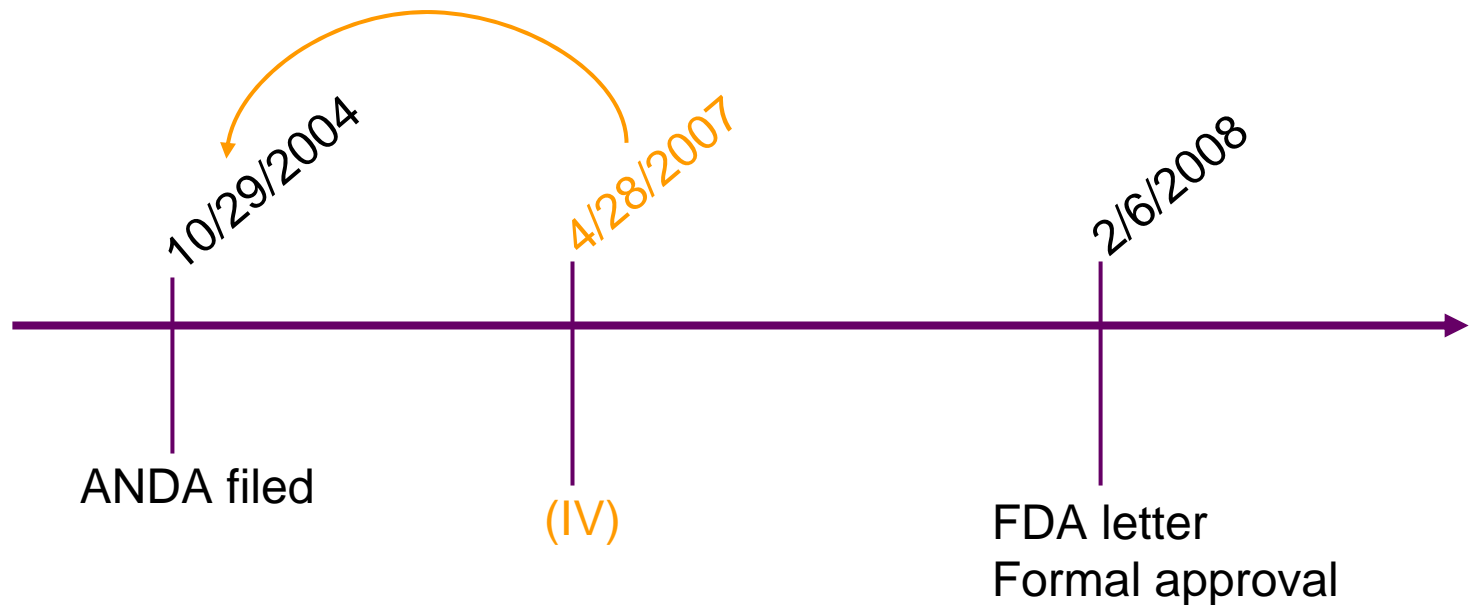
Sandoz: Metoprolol Succinate ER



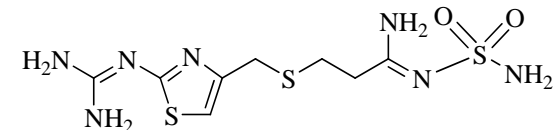
“However, the agency is not making a formal determination at this time of Sandoz’s eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Sandoz begins commercial marketing Metoprolol Succinate Extended-Release Tablets USP, 25 mg.”



Perrigo: Famotidine

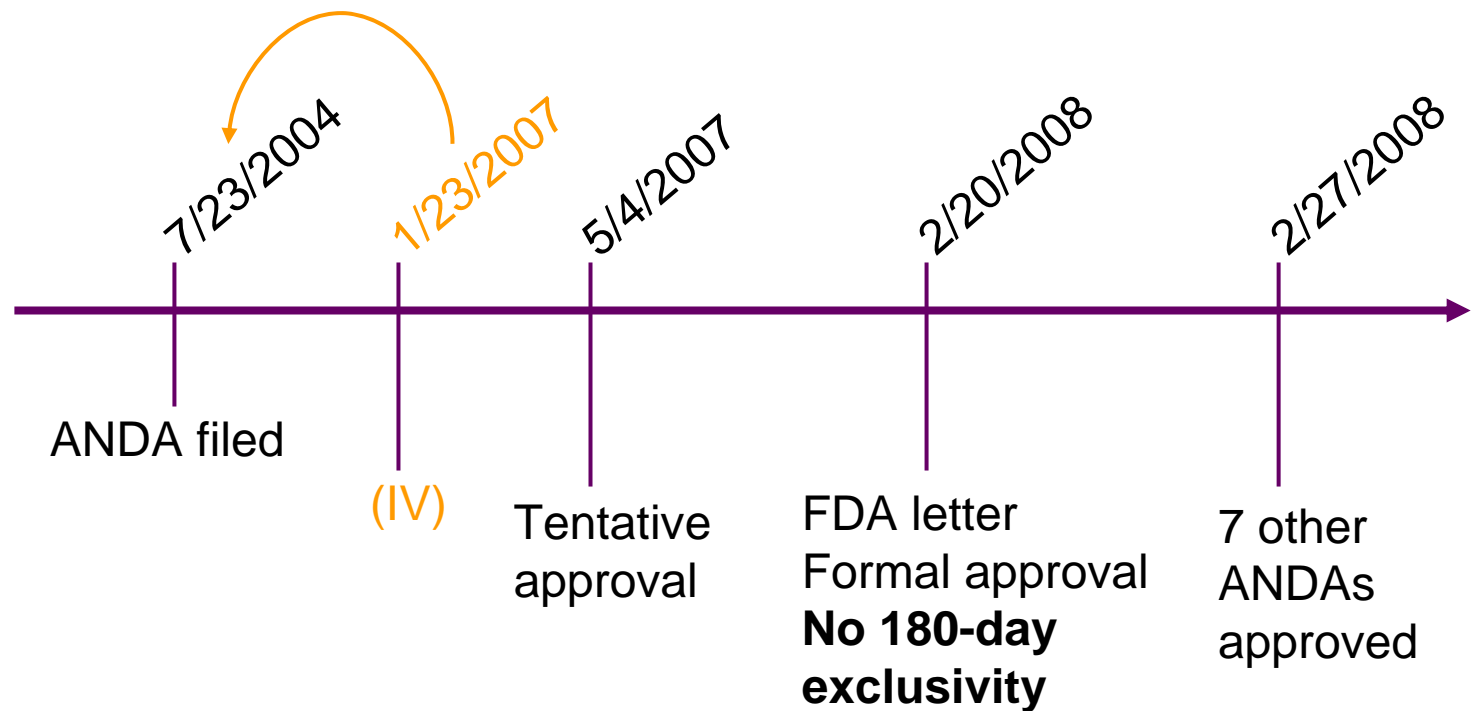


“However, the agency is not making a formal determination at this time of Perrigo's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Perrigo begins commercial marketing of Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC).”

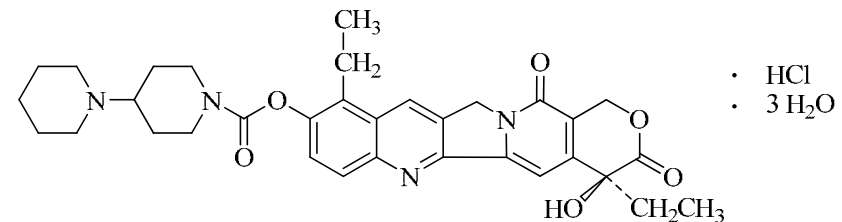


...unless someone hears it.

Watson: Irinotecan Hydrochloride



“We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act for Irinotecan Hydrochloride Injection, 20 mg/mL, **was forfeited by Watson.**”



Links to the FDA Letters can be found at:

www.merchantgould.com/CM/Events/WDWPresentation.asp

Thank you.

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