

# FDA Proposed Rule Implementing the Medicare Modernization Act

March 6, 2015

Food & Drug

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## Introduction

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On February 6, 2015, FDA published a long-awaited proposed rule (accompanied by a lengthy preamble)<sup>1</sup> to implement the 2003 Medicare Prescription Drug, Improvement, and Modernization Act's (the "MMA's")<sup>2</sup> amendments to the Food, Drug, and Cosmetic Act ("FDCA"). Since 2003, FDA has been implementing the MMA directly from the statute. The proposal addresses a wide range of topics, including submission of patent information, patent listing and certification requirements, availability of 30-month stays, amendments and supplements to 505(b)(2) applications and ANDAs, definitions, and organizational and other clarifying edits. FDA is seeking comments on the proposed rule by May 7, 2015.

Although FDA characterizes the proposed rule as implementing portions of the MMA that pertain to 30-month stays "and other matters not related to 180-day exclusivity," some of the proposed regulations would affect the availability of and triggering of 180-day exclusivity. The agency states that it will consider in the future whether additional rulemaking is necessary to implement the 180-day exclusivity provisions of the MMA.

FDA is proposing to codify a number of policies that the agency has developed over the past 12 years, as well as to take new positions on certain matters. This alert focuses on the proposals that deviate from FDA's prior approaches or that might otherwise be of particular interest to industry.

## Highlights of Major Changes

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Several of FDA's proposals are particularly noteworthy.

First, with respect to reissued patents, the agency is proposing to treat the original and reissued patents as a "single bundle" of patent rights. This treatment has consequences for the administration of patent certification requirements under the FDCA and any 30-month stay of approval or 180-day exclusivity that relates to a paragraph IV certification to the original patent.

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<sup>1</sup> 80 Fed. Reg. 6802 (February 6, 2015).

<sup>2</sup> Public Law 108-173, 117 Stat. 2066.

As to 30-month stays, if a 505(b)(2) or ANDA applicant submitted a paragraph IV certification to the original patent and a patent infringement action was initiated within 45 days of receipt of the applicant's notice of paragraph IV certification, reissuance of the patent would not affect the 30-month stay; *i.e.*, there would be no subsequent stay. If a 505(b)(2) or ANDA applicant submitted a paragraph IV certification to the original patent and no patent infringement action was initiated within the 45-day period, a later infringement action regarding the reissued patent could *not* give rise to a 30-month stay. If a 505(b)(2) or ANDA applicant submitted a section viii statement or a paragraph III certification to the original patent and a paragraph IV certification to the reissued patent, a 30-month stay would be available if an infringement action were initiated within 45 days of the applicant's notice of paragraph IV certification to the reissued patent. FDA also notes that, if a 505(b)(2) or ANDA applicant did not need to certify to the original patent because it was late listed, the applicant would not have to certify to the reissued patent, even if timely filed after reissuance.

FDA explains that if one or more first applicants is eligible for 180-day exclusivity based on a paragraph IV certification to the original patent and the patent is reissued, the first applicant would need to submit a paragraph IV certification to the reissued patent within 30 days of listing to remain eligible for exclusivity. If no ANDA applicant submitted a paragraph IV certification to the original patent, however, the first ANDA applicant to submit such a certification to the reissued patent could be eligible for 180-day exclusivity (if no other applicant already qualified as a first applicant based on an earlier paragraph IV certification to another listed patent).

Second, the proposed rule would specify the timeframe during which notice of a paragraph IV certification must be given and impose an administrative penalty for noncompliance. This proposal is intended to discourage ANDA applicants from providing serial, premature paragraph IV notices. Under the proposed rule, an applicant could not send the paragraph IV notice until FDA notified the applicant that its application had been filed or received, as appropriate. Applicants would have to give notice no later than 20 days after the date of the postmark on FDA's letter. Notice would be invalid if sent before the first working day after the day the patent is listed in the Orange Book.

If an ANDA applicant failed to timely provide notice, FDA would deem the date of submission of the ANDA to be moved forward by the number of days by which the timeframe was exceeded. Thus, if an ANDA applicant provided late notice, it might lose its first applicant status and thus its eligibility for 180-day exclusivity. This adjusted date of submission also would be used to calculate the deadline for receiving tentative approval to avoid forfeiture of 180-day exclusivity.

Third, FDA proposes changes to curtail the perceived use of overbroad patent use codes (NDA applicants' descriptions in the Orange Book of patented methods of use). Under the proposal, if the scope of a patent's method-of-use claim(s) does not cover all uses of the drug, an applicant would have to identify the specific sections of drug labeling that correspond to the specific portion(s) of the indication or other condition of use claimed by the patent. This would effectively require innovators to identify, at the time of patent listing, the parts of labeling they believe ANDA applicants would need to carve out due to a particular method-of-use patent. FDA further proposes that an NDA holder's amendment to a use code would be deemed untimely filed if it is: (1) submitted more than 30 days after patent issuance and it is not related to a corresponding change in drug labeling, or (2) submitted more than 30 days after a corresponding change in

drug labeling. According to FDA, this proposal “is intended to reduce delays in approval related to manipulation of patent use codes in a manner not contemplated by the [FDCA].”<sup>3</sup>

In response to disputes about listed method-of-use patents, FDA proposes that, within 30 days of FDA’s request, an NDA holder would need to confirm the correctness of the use code and provide information on the specific approved use claimed by the patent. If the NDA holder confirmed the accuracy of the patent information, failed to timely respond to FDA’s request, or submitted a revision to the use code that did not provide adequate clarity for FDA to determine whether a 505(b)(2) or ANDA applicant’s proposed labeling would be appropriate, FDA would review the proposed labeling with deference to the applicant’s interpretation of the scope of the patent.<sup>4</sup> FDA believes that “enhancing the mechanism for challenging overbroad use codes listed in the Orange Book may cause NDA holders to be more circumspect in their original submission of patent information to FDA.”<sup>5</sup>

Fourth, FDA proposes clarifying the effect of a preliminary injunction on a 30-month stay. If a preliminary injunction were entered before expiry of a 30-month stay, the stay of approval would be extended until the court decided the issues of patent infringement and validity.

Finally, FDA proposes revising its regulations to reflect that, under the MMA, the date of first commercial marketing by a first applicant alone triggers the start of the 180-day exclusivity period. FDA proposes requiring a first applicant to submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing of the drug. If the first applicant failed to timely provide this notice, FDA would deem the date of first commercial marketing to be the date of the drug product’s approval, which could effectively shorten the 180-day period.

## Major Proposals by Topic

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### Submission of Patent Information (Proposed § 314.53)

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#### General Requirements

##### Drug Substance (Active Ingredient) and Drug Product (Formulation or Composition) Patents

- FDA proposed to add the following exceptions to the required submission of patent information:
  - If a patent claims the drug substance that is the active ingredient in the drug product, it is not necessary for an applicant to provide information on whether the patent also claims the drug product.

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<sup>3</sup> 80 Fed. Reg. at 6803.

<sup>4</sup> FDA states that ANDA applicants have “a strong incentive to interpret the scope of the patent correctly to avoid being subject to patent infringement litigation following ANDA approval and potentially enjoined from marketing its product.” *Id.* at 6828.

<sup>5</sup> 80 Fed. Reg. at 6828.

- If a patent claims the drug product, it is not necessary for an applicant to provide information on whether the patent also claims the drug substance that is the active ingredient in the drug product.
- An NDA applicant that submitted information for a method-of-use patent would continue to be required to submit information regarding whether that patent also claims either the drug substance or the drug product. An ANDA applicant seeking to “carve out” a method of use claimed by the patent would still be required to submit a patent certification with respect to any drug substance or drug product claims covered by the same listed patent.
- Proposed revisions would require an applicant to provide information on whether a drug substance patent claims a polymorph that is the same active ingredient described in the pending NDA, amendment, or supplement only if patent is eligible for listing solely on the basis that it claims the polymorph.

#### Method-of-Use Patents

- The proposed rule would codify the requirement that use codes contain adequate information to assist FDA and 505(b)(2) and ANDA applicants in determining whether a patent claims a use for which the applicant is not seeking approval.
- FDA proposes revisions to require that, if the scope of the method-of-use claim(s) of a patent does not cover every use of the drug, the applicant would need to identify the specific drug labeling content that corresponds to the specific portion(s) of the indication or other condition of use claimed by the patent. This content may appear in sections of the drug labeling other than the “Indications and Usage” section.

#### Reissued Patents

- FDA acknowledges that the original patent is surrendered upon patent reissuance, but it proposes treating the original patent and the reissued patent as a “single bundle” of patent rights for purposes of administering the FDCA. Thus:
  - If a 505(b)(2) or ANDA applicant was not required to certify to the original patent because the patent was late listed, the applicant would not have to certify to the reissued patent, even if timely filed following reissuance.
  - The date of submission of the original patent information (rather than the submission of the reissued patent information) would determine the ultimate availability of a 30-month stay.
  - If a 505(b)(2) or ANDA applicant submitted a paragraph IV certification to the original patent and no infringement action was initiated within the 45-day period, no later infringement action regarding the reissued patent could result in a 30-month stay.
  - If no applicant submitted a paragraph IV certification to the original patent, the first ANDA applicant to submit a paragraph IV certification to the reissued patent could be eligible for 180-day exclusivity (if no other applicant already had qualified as a first applicant based on an earlier paragraph IV certification to another listed patent).
  - If one or more first ANDA applicants were eligible for 180-day exclusivity based on a paragraph IV certification to the original patent and the patent is reissued, a first ANDA applicant must submit a paragraph IV certification to the reissued patent within 30 days of listing to maintain exclusivity eligibility.

- An original patent that has been reissued would remain listed in the Orange Book until FDA determined that no first applicant was eligible for 180-day exclusivity or 180-day exclusivity had expired. FDA would designate the original patent with a suffix (“\*RE”) in the Orange Book.

## **When and Where to Submit Patent Information**

### Submission of Patent Information for NDA Supplements

- Sponsors would continue to submit information for a patent that claims the drug substance, drug product, or method of use for which approval is sought in a supplement when the supplement would result in a new entry in the Orange Book, such as to change: (A) the dosage form or route of administration; (B) the strength; or (C) the drug product from prescription to over-the-counter use.
- If an applicant submitted a supplement for a change that would not result in a new entry in the Orange Book, however, the applicant would need to evaluate whether each currently listed patent for the drug product continues to claim the changed product:
  - If previously submitted patent information claimed the changed product, the applicant would not have to resubmit this patent information unless the use code would change upon approval of the supplement. FDA would continue to list this patent information for the product.
  - If previously submitted patent information no longer claims the changed product, the applicant would have to submit a request to remove that patent information from the Orange Book at the time of supplement approval.
  - If existing drug substance, drug product, or method-of-use patents claimed the changed drug product and such patent information had not been submitted to FDA, the applicant would need to submit the required patent information.

### Untimely Filing of Patent Information

- An NDA holder’s amendment to change a patent use code would be considered untimely filed if the amendment: (1) were submitted more than 30 days after patent issuance (or reissuance) and did not relate to a corresponding change in approved product labeling, or (2) were submitted more than 30 days after a corresponding change in approved product labeling.

### Where to Send Submissions of Forms FDA 3542a and 3542

- FDA proposes that patent information filed on Form FDA 3542 upon and after approval of an NDA or supplement be submitted directly to the Orange Book staff through the Office of Generic Drugs (OGD) Document Room.
- Patent information submitted on Form FDA 3542a with the filing of an NDA, amendment, or supplement, and prior to approval of the application, would continue to be submitted directly to the NDA by submission to the Central Document Room, Center for Drug Evaluation and Research (CDER).
- Patent information will be considered to be submitted to FDA as of the earlier of the date the information submitted on FDA 3542 is date-stamped by OGD or officially received electronically by FDA through the electronic Gateway. The preamble and proposed rule suggest that submission through the electronic Gateway is permitted, but are unclear on

whether such a submission can be made to satisfy the requirements to submit patent information to the OGD or CDR as noted above.

#### Public Disclosure of Patent Information

- FDA is considering proactively posting on its website a copy of Form FDA 3542 for patents listed in the Orange Book. Historically, this information has been obtained primarily through FOIA requests or litigation.

#### **Correction or Change of Patent Information**

##### Requests by Persons Other than the NDA Holder

- FDA proposes that if any person disputes the accuracy or relevance of listed patent information, that person must first notify the Orange Book Staff and state the grounds for disagreement. FDA would then request that the NDA holder confirm the correctness of the patent information within 30 days.
- For listed method-of-use patents, FDA would request that the NDA holder confirm the correctness of the use code in the Orange Book and provide information on the specific approved use claimed by the patent, to enable FDA to determine whether the scope of a proposed labeling carve-out would be appropriate.
- Unless the NDA holder withdrew or amended its patent information in response to FDA's request to confirm the correctness of the patent information, FDA would not change the patent information in the list.
- Nevertheless, if the NDA holder confirmed the accuracy of the patent information, failed to timely respond to FDA, or submitted a revised use code that did not provide adequate clarity for FDA to determine whether the scope of a proposed labeling carve-out would be appropriate based on the NDA holder's use code and approved labeling, FDA would review the proposed labeling for the 505(b)(2) application or ANDA with deference to the applicant's interpretation of the scope of the patent.

##### Requests by NDA Holder to Remove Patent Information and Patent Term Restoration

- If an NDA holder is required by court order to amend patent information or withdraw a patent from the list, FDA proposes that the NDA holder must submit a copy of the order to FDA within 14 days of order entry. FDA would remove a patent from the list if there were no first applicant eligible for 180-day exclusivity or upon expiry of such exclusivity.
- If the term of a listed patent is extended under 35 U.S.C. § 156(e), the NDA holder would need to correct the expiration date by submitting Form FDA 3542 within 30 days of receipt of a certificate of extension or documentation of an extension of the patent term.

## **Notice of Paragraph IV Certification (Proposed §§ 314.52 and 314.95)**

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#### **Timing of Notice**

##### Date Before Which Notice May Not Be Given

- In an effort to discourage premature notices, FDA proposes to clarify that a 505(b)(2) or ANDA applicant cannot send notice of a paragraph IV certification until FDA has notified



the applicant that its application has been filed or received, as appropriate, in an acknowledgment letter or a paragraph IV acknowledgment letter.

- Any notice sent before the receipt of an FDA acknowledgment letter or paragraph IV acknowledgment letter would be invalid.
- To ensure that all ANDA applicants (irrespective of time zone) have a reasonable opportunity to be a first applicant with respect to a newly listed patent, FDA proposes that any notice of paragraph IV certification would be invalid if it is sent before the first working day *after* the day the patent is listed in the Orange Book.
- An invalid notice would not trigger either the 45-day period for bringing an infringement action to obtain a 30-month stay or any related 30-month period. To qualify for 180-day exclusivity, an applicant would need to resend notice within the required timeframe.
- An applicant that submits an amendment containing a paragraph IV certification before receiving an acknowledgment letter or paragraph IV acknowledgment letter for its original application could not send a valid paragraph IV notice until it receives that letter.

#### Date by Which Notice Must Be Given and Administrative Consequence for Late Notice

- If a paragraph IV certification was included in an original 505(b)(2) application or ANDA (or in an amendment to such application submitted before the applicant receives an acknowledgment letter or paragraph IV acknowledgment letter), then the applicant would have to give notice no later than 20 days after the date of the postmark (as defined in the proposal) on the notice from FDA informing the applicant that its application has been filed or received.
- If the paragraph IV certification were included in any other amendment or in a supplement, the applicant would have to give notice on the same day that the applicant submits the amendment or supplement. In determining first applicant eligibility for 180-day exclusivity based upon an ANDA applicant's submission of a paragraph IV certification in an amendment, the relevant date is the date on which the amendment was officially received (*i.e.*, date stamped) by the OGD document room.
- For an ANDA applicant that failed to timely provide notice of a paragraph IV certification, FDA would deem the date of submission of the ANDA to be moved forward by the number of days by which the required timeframe was exceeded. Thus, an ANDA applicant could lose its first applicant status and thus its eligibility for 180-day exclusivity, if another applicant submitted a substantially complete ANDA with a paragraph IV certification on the same first day and provided timely notice.<sup>6</sup>

#### **Contents of Notice**

- Proposed revisions would require specified additional information in a notice of paragraph IV certification, including a statement that the applicant has received an

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<sup>6</sup> FDA declined to propose an administrative consequence for 505(b)(2) applicants that provide untimely notice, noting that 505(b)(2) applicants are not eligible for 180-day exclusivity and that, due to PDUFA goals, FDA is unable to extend the review clock as an administrative consequence.

acknowledgment letter or paragraph IV acknowledgment letter for the ANDA or 505(b)(2) application.<sup>7</sup>

### **Documentation of Timely Sending and Receipt of Notice**

- FDA proposes that all 505(b)(2) and ANDA applicants could send notice of paragraph IV certification by the U.S. Postal Service or a “designated delivery service.” FDA would issue guidance that describes services qualifying as designated delivery services.
- An applicant would have to amend its 505(b)(2) application or ANDA to provide documentation of the date that each patent owner and NDA holder received the notice of paragraph IV certification. The applicant would have to submit the amendment within 30 days after the last date on which notice was received by a patent owner or NDA holder.
- Documentation showing that a paragraph IV certification was submitted and notice was sent only for patents listed in the Orange Book would have to be submitted by an ANDA applicant in its amendment certifying that notice of paragraph IV certification had been made. An ANDA applicant would have to include a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the notice of paragraph IV certification. A 505(b)(2) applicant may elect to do the same.

## **Amended Patent Certifications (Proposed §§ 314.50(i)(6) and 314.94(a)(12)(viii))**

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### **Amended Certifications After Request by NDA Holder to Remove Patent Information**

- If an NDA holder requests removal of patent information from the Orange Book, FDA would remove that information if no ANDA applicant is eligible for 180-day exclusivity.
- A 505(b)(2) applicant would not need to provide or maintain a certification to a patent that remains listed only for purposes of a first applicant’s 180-day exclusivity (because a 505(b)(2) applicant is neither eligible for nor blocked by such exclusivity).

### **Amended Certifications Upon Patent Reissuance**

- A 505(b)(2) or ANDA applicant would have to certify to a reissued patent, unless either the original patent or the reissued patent was not timely filed by the NDA holder.
- If an ANDA applicant submitted a paragraph IV certification to the original listed patent and believed that a paragraph IV certification to the reissued patent was appropriate, the

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<sup>7</sup> FDA recognizes that this proposed requirement may have the effect of delaying the provision of notice of paragraph IV certification by a 505(b)(2) applicant (but not an ANDA applicant) by approximately two weeks after the 505(b)(2) application is filed. This is because, while a 505(b)(2) application is considered filed 60 days after submission, FDA’s proposed definition of a “paragraph IV acknowledgment letter” for a 505(b)(2) application is the filing communication that is generally mailed by the 74th day after submission, in accordance with current performance goals. FDA recognizes that this would potentially delay the initiation of patent infringement litigation by an NDA holder or patent owner and any corresponding 30-month stay of approval of the 505(b)(2) application by approximately two weeks.



applicant would have to amend its pending ANDA to contain a paragraph IV certification to the reissued patent within 30 days of listing of the reissued patent to lawfully maintain its paragraph IV certification for purposes of eligibility for 180-day exclusivity.

## **Patent Certification Requirements for Amendments and Supplements (Proposed §§ 314.60, 314.70, 314.96, and 314.97)**

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### **Amendments or Supplements for Which New Patent Certification is Required**

- An amendment to a 505(b)(2) application or ANDA would need to contain patent certifications if approval were sought for: (1) a new indication or other condition of use; (2) a new strength; (3) other-than-minor changes in product formulation; or (4) a change the physical form or crystalline structure of the active ingredient. If an applicant does not provide a new certification for one of these categories of changes, the applicant would have to verify that the proposed change does not trigger the requirement for a new certification (e.g., it is a minor formulation change).
- For instance, the applicant would not have to provide a new patent certification if the new formulation is qualitatively (Q1) the same as the previous formulation (contains all of the same inactive ingredients) and quantitatively (Q2) essentially the same (each inactive ingredient differs by no more than plus or minus 5 percent from the previous formulation).
- FDA proposes that a supplement to a 505(b)(2) application or ANDA be required to contain patent certifications if approval is sought for a supplement: (1) to add a new indication or other condition of use; or (2) to add a new strength.
- A supplement to a 505(b)(2) application to add a new indication or other condition of use would have to contain patent certifications only for patents that are identified as claiming an approved use. If the method-of-use patent also claims the drug substance or drug product, the patent certification also would need to address those claims.

### **Implications for 180-Day Exclusivity**

- A first applicant that submitted an amendment to its pending ANDA or a supplement would be considered to have lawfully maintained a paragraph IV certification to the patent upon which its eligibility for 180-day exclusivity was based if the amendment or supplement were accompanied by another paragraph IV certification to that patent and notice of the paragraph IV certification was timely given.

## **Amendments or Supplements to a 505(b)(2) Application for a Different Drug and to an ANDA that References a Different Listed Drug (Proposed §§ 314.60, 314.70, 314.96, and 314.97)**

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### **Restrictions on Submission of Amendments or Supplements**

- Proposed section 314.96(c) would state that an applicant may not amend an ANDA to refer to a different listed drug. This requirement could be implicated in two scenarios: (1)

if, before an ANDA is approved, an NDA is approved for a drug product that is pharmaceutically equivalent to the ANDA product and is designated as a reference listed drug; or (2) if an ANDA amendment proposes a change that would result in the proposed product being a pharmaceutical equivalent to a different listed drug. In both cases, the applicant would have to submit a new ANDA.

- Proposed section 314.60(e) would provide that a 505(b)(2) applicant could not amend its application to seek approval of a drug that is a “different drug” from the drug in the original 505(b)(2) application. FDA proposes that a drug is a “different drug” requiring a new application if it has been modified to have a different active ingredient, route of administration or dosage form or a difference in excipients requiring a separate clinical study to establish safety or effectiveness or, in the case of topical products, that requires a separate in vivo demonstration of bioequivalence. This restriction would apply to any amendment, even if submitted before FDA’s filing decision for the 505(b)(2) application.

### **Listed Drugs Identified in Section 505(b)(2) Application (Proposed § 314.54)**

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- FDA proposes that a 505(b)(2) application would have to identify, as a listed drug, any approved product that: (1) is pharmaceutically equivalent to the proposed product; and (2) was approved before submission of the 505(b)(2) application. This obligation would not apply if FDA approved the pharmaceutical equivalent *after* submission of the 505(b)(2) application.<sup>8</sup>

### **Tentative and Final Approval (Proposed §§ 314.105 and 314.107)**

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- The proposal would clarify that a drug with tentative approval is not an approved drug and that FDA does not issue approval letters with delayed effective dates. Proposed revised section 314.105(a) and (d) state expressly that a tentative approval is based on information available to the agency at the time of the tentative approval letter and is subject to change based on new information that comes to FDA’s attention.
- If FDA issued an approval letter in error or if a court entered an order requiring a delay in approval of an already-approved 505(b)(2) application or ANDA, FDA would convert the approval to tentative approval if appropriate.

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<sup>8</sup> This requirement is intended to ensure that “the 505(b)(2) pathway is not used to circumvent the statutory obligation that would have applied if the proposed product was submitted as an ANDA—namely, submission of a patent certification for a listed patent that corresponds to the protected aspects of the pharmaceutically equivalent listed drug.” 80 Fed. Reg. at 6856.

## Implementation of the 30-Month Stay (Proposed § 314.107)

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### Limitation on Multiple 30-Month Stays

- Proposed revised section 314.107(b)(3)(i) would clarify that no 30-month stay would arise from an action for infringement of a patent submitted to FDA on or after the date that the 505(b)(2) application or ANDA was first submitted. In determining whether a patent was submitted to FDA before a 505(b)(2) application or ANDA submission, FDA would rely on the date the patent was submitted to FDA and not on the date the patent is published in the Orange Book.
- FDA notes that there still could be instances where multiple 30-month stays may be possible. FDA cites an example it has previously identified in a draft guidance<sup>9</sup>: If an original 505(b)(2) application or ANDA contained a paragraph IV certification to a patent that resulted in a 30-month stay and also contained a paragraph III certification to a different patent that was submitted to FDA before the 505(b)(2) application or ANDA was submitted, the applicant could receive a second 30-month stay if it subsequently amended the paragraph III certification to a paragraph IV certification. As another example, a second 30-month stay could result from initiation of litigation in response to a second notice of paragraph IV certification accompanying an amendment or supplement to a 505(b)(2) application or ANDA, if the patent was listed prior to the date of submission of the original 505(b)(2) application or ANDA and the infringement action was warranted by the change proposed in the amendment or supplement.

### Beginning of 30-Month Stay

- FDA proposes to clarify in section 314.107(b)(3)(i) that a 30-month stay of approval begins on the later of the date of receipt of the paragraph IV certification by any owner of the listed patent or by the NDA holder who is an exclusive patent licensee (or their representatives). This proposal appears intended to maximize the length of the 30-month stay.

### Grant of Preliminary Injunction by Federal District Court

- If a preliminary injunction were entered before expiry of a 30-month stay, the stay of approval would be extended until the court decided the issues of patent infringement and validity.

## Changes to 180-Day Exclusivity Trigger and Forfeiture (Proposed § 314.107(c))

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- FDA proposes revising section 314.107(c)(3) to reflect that, per the MMA, the “date of the first commercial marketing of the drug (including commercial marketing of the listed

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<sup>9</sup> FDA Draft Guidance for Industry, *Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (October 2004).

drug) by any first applicant” is the sole exclusivity trigger. The proposal would require a first applicant to submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing. If the first applicant failed to timely provide this notice, FDA would deem the date of first commercial marketing to be the date of the drug product’s approval, potentially shortening the 180-day period.

- FDA proposes deleting section 314.107(c)(3), which states that a first applicant’s failure to “actively pursue” approval of its ANDA may result in the loss of its eligibility for 180-day exclusivity. FDA explains that this provision has been “superseded” by the forfeiture provisions added to the FDCA by the MMA.

### **Notification of Court Actions or Documented Agreements (Proposed § 314.107(e))**

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- FDA proposes to require 505(b)(2) and ANDA applicants to submit to the agency copies of certain documents related to court judgments, settlements, or consent decrees in patent litigation, including orders terminating the 30-month stay and orders related to preliminary injunctions. If an applicant is uncertain whether a particular court action or agreement requires FDA notification, FDA recommends submission.
- All required information would need to be submitted within 14 calendar days of entry by the court, the date of appeal or expiration of the time for appeal, or the date of written agreement, as applicable.

### **45-Day Period After Receipt of Notice of Paragraph IV Certification (Proposed § 314.107(f))**

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- FDA proposes codifying that the 45-day period after receipt of notice of paragraph IV certification would be calculated for each recipient required to be notified. Where the NDA holder and patent owner(s) are different entities and receive notice of paragraph IV certification on different days, this could result in more than one 45-day clock.
- The proposal would require that a 505(b)(2) or ANDA applicant notify FDA within 14 calendar days of the filing of any legal action within 45 days of receipt of the notice of certification. This would replace the current requirement of “immediate” notification.
- An NDA holder or its representative could notify FDA of the filing of any legal action for patent infringement, irrespective of whether the NDA holder is the exclusive patent licensee and initiated the patent infringement action. A patent owner or NDA holder who is an exclusive patent licensee also could expressly waive the opportunity to bring suit within the 45-day period.

## **Conclusion**

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FDA’s proposed rule would codify and expand its policies for implementing various portions of the MMA. It contains many detailed provisions critical to implementation of the Hatch-Waxman scheme. We would be pleased to discuss the proposal and its potential effect on your company.

## Food & Drug

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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