U.S. FOOD & DRUG ADMINISTRATION

"Minor" Regulatory Errors with Major Consequences

Thu 'Suzanne' Phan, PharmD
Pharmacist, Patent and Exclusivity Team
Division of Legal and Regulatory Support (DLRS), Office of Generic Drug Policy (OGDP), Office of Generic Drugs (OGD)
CDER | US FDA

SBIA Generic Drug Forum 2025 – April 9 - 10, 2025

Learning Objectives

- Review the requirements for proper documentation of notice of PIV certification under 21 CFR 314.95
- Review patent certification requirements under 21 CFR 314.94(a)(12)(vi)
- Other Reminders
  - Docket Numbers
  - 356h Forms

Common Issues

- Notice documents missing, not provided to FDA
- Notice documents don’t align or are incomplete – was notice appropriately provided?
- Notifying FDA if litigation is or is not filed within the 45-day period after receipt of notice

Notification of PIV Certification - Original Submission

Section 505(j)(2)(B); 21 CFR 314.95

- Applicant must **send notice** of Paragraph IV certification to each owner of the patent that is the subject of the PIV certification and the NDA holder within **20 days** after the date of the postmark on the PIV acknowledgment letter
- Applicant must submit documentation of timely sending and receipt of notice

Documentation of Notice - Original Submission 21 CFR 314.95(e)

Applicants that file a **paragraph IV patent certification** must subsequently amend their ANDA to **provide documentation to FDA** regarding

(1) their **notice of certification that was received by** the patent owner(s) and NDA holder and

(2) **any legal action** that has been taken against the applicant under that paragraph IV notice.

Specifically, applicants must amend their ANDA to provide documentation:

- That their notice of a paragraph IV certification **was sent** on a date that complies with the time frame provided in the regulations for sending this notice
- Of the date that this notice **was received** by the patent owner(s) and NDA holder
- Documentation of receipt **must be submitted** to the ANDA **within 30 days** after the last date on which the notice was received by the patent owner(s) and NDA holder.

Potential Impact: Failure to submit documentation of receipt of notice may result in delays to FDA action on your ANDA or result in issuing an 'policy only' complete response letter.

What Constitutes Adequate Documentation of Notice? 21 CFR 314.95(e)

- Adequate documentation of the **date the notice was sent**
  - A copy of the registered mail receipt
  - Certified mail receipt, or
  - Receipt from a designated delivery service
- Adequate documentation of the **delivery of notice**
  - **Date of receipt a return receipt**
  - **Signature proof of delivery** by a designated delivery service, or
  - A letter acknowledging receipt by the person provided the notice

Designated Delivery Service

Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number
[redacted]

Service
[redacted]

Additional Information
Signature Required

Delivered On
05/11/2022 12:42 P.M.

Delivered To
[redacted]

Weight
3.00 LBS

Shipped / Billed On
05/09/2022

Received By
[redacted]

Left At
[redacted]

[redacted]

February 15, 2022

Dear Customer,

The following is the proof-of-delivery for tracking number: [redacted]

Delivery Information:

Status:	Delivered	**Delivered To:**	Shipping/Receiving
Signed for by:	[redacted]	**Delivery Location:**	[redacted]
Service type:	FedEx Standard Overnight		
Special Handling:	Deliver Weekday; Adult Signature Required		LAKE ZURICH, IL, 60047
		Delivery date:	Feb 15, 2022 08:49

Shipping Information:

Tracking number:	[redacted]	**Ship Date:**	Feb 14, 2022
		Weight:	1.0 LB/0.45 KG

Recipient:
[redacted]

Shipper:
[redacted]

Reference [redacted]

Addressing Later-Listed Patents and Patent Information 21 CFR 314.94(a)(12)(vi)(A)

- An applicant must address all new, timely filed patents and patent information listed in the Orange Book after its application has been received with one of the patent certifications or section viii statement, as applicable
- **New** or updated patent listings require **new** certifications or statements
- Prior PIV certification for the same patent does not sufficiently address newly listed patent information (e.g., use code)

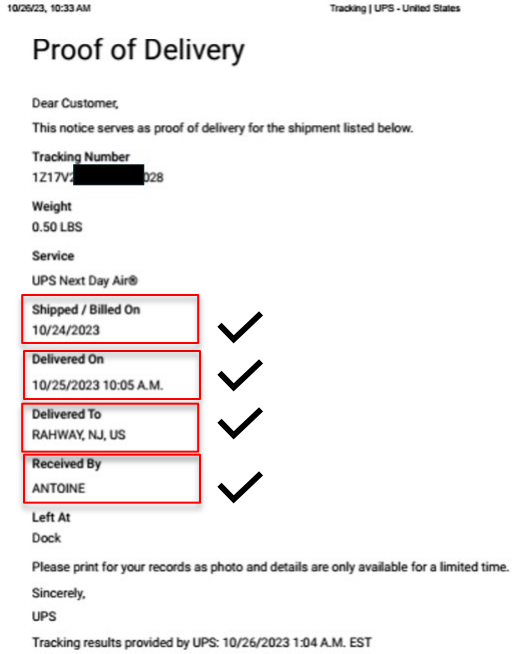
PIV Certifications Submitted After Original Submission of ANDA – Notice Requirements 21 CFR 314.95(d)

- Notice must be sent at the **same time as** submission of the PIV certification
- **Potential Impact:**
  - Failure to address new or updated patent listing or provide documentation of receipt of notice can result in **a complete response letter** from the FDA
  - FDA cannot take tentative or final approval of the ANDA until proper notice has been sent and documentation of receipt of notice by NDA holder(s) and patent owner has been received by FDA

Challenge Question #1

Which of these is the **NOT** an acceptable form of documentation of notice?

a.



10/26/23, 10:33 AM Tracking | UPS - United States

Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number
1Z17V[redacted]028

Weight
0.50 LBS

Service
UPS Next Day Air®

Shipped / Billed On
10/24/2023

Delivered On
10/25/2023 10:05 A.M.

Delivered To
RAHWAY, NJ, US

Received By
ANTOINE

Left At
Dock

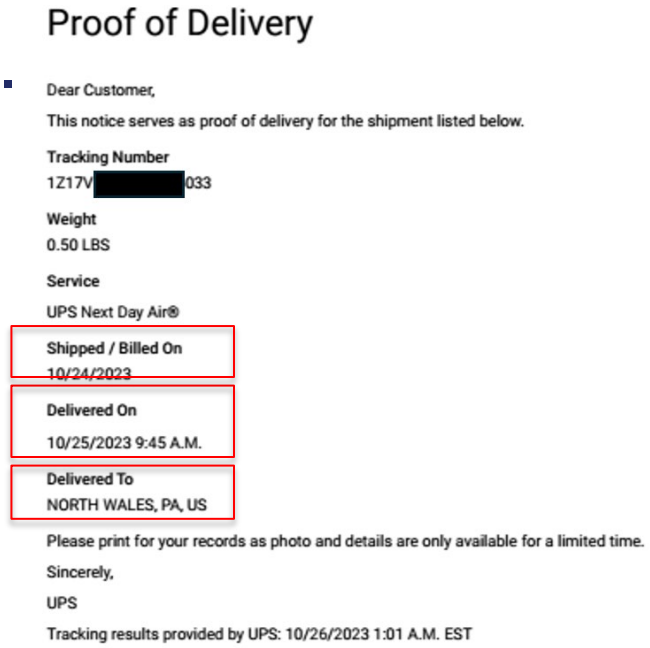
Please print for your records as photo and details are only available for a limited time.

Sincerely,

UPS

Tracking results provided by UPS: 10/26/2023 1:04 A.M. EST

b.



Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

Tracking Number
1Z17V[redacted]033

Weight
0.50 LBS

Service
UPS Next Day Air®

Shipped / Billed On
10/24/2023

Delivered On
10/25/2023 9:45 A.M.

Delivered To
NORTH WALES, PA, US

Please print for your records as photo and details are only available for a limited time.

Sincerely,

UPS

Tracking results provided by UPS: 10/26/2023 1:01 A.M. EST

Challenge Question #2

If a **new patent or use code** is listed in the FDA's **Orange Book** after an ANDA has already been submitted, **when must an applicant send the required notice** after submitting an amendment to its ANDA that includes a **Paragraph IV certification**?

A) Within 30 days of the new patent or use code being listed in the Orange Book.

B) **At the same time** that the amendment to the ANDA is submitted to FDA.

C) Only **after receiving FDA approval** of the ANDA application.

D) **No notice is required** for later-listed patents or use codes.

Other Reminders

Notification of Filing of Legal Action – Original Submission

- **21 CFR 314.107(f)(2):** A statement that an action for patent infringement, identified by court, **case number**, and the patent number(s) of the patent(s) at issue in the action, has been filed in an appropriate court on a specified date
- **21 CFR 314.107(b)(1)(i)(C):** If **no legal action** for patent infringement has been filed within the noted 45-day period, submit an amendment to notify FDA **AFTER** the expiration of the 45-day period
- **Potential Impact:** Delays in issuing a tentative or final approval action

Who Must Sign Form 356h?

21 CFR 314.94(a)(1)

- **Primary Signature (Field 37):** Must be signed by the applicant or an authorized official (e.g., attorney, agent).
- **Additional Requirement for Non-U.S. Applicants (Field 38):** If the applicant does not reside or have a place of business in the U.S., an authorized U.S.-based representative must countersign
- Every 356h **must be signed**

Key Takeaways

1. Double-check to make sure you submit **adequate documentation** that complies with the requirements of **21 CFR 314.95 when submitting a PIV certification**

   – If you submit a Paragraph IV certification, you must send notice to the NDA and patent holder(s)

   – Once you sent notice, inform the FDA and submit **documentation and receipt of notice** to the FDA

2. Include either a patent certification or section viii statement for *each* patent and patent information listed in the Orange Book for the RLD as required under **21 CFR 314.94(a)(12)(vi)**

3. **Bottom Line**: **Overlooking any of these can result in delayed action**

Questions?

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