Addressing Patent and Exclusivity Requirements – Regulatory Reminders

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Overview

- Review regulatory requirements related to the most common patent and exclusivity deficiencies, including:
  - Addressing later-listed patents/patent information and new exclusivities
  - Adequate documentation of notice of paragraph IV certification
  - Notification of the filing of legal action, court orders and licensing agreements
  - Pediatric Exclusivity
- Discuss timely notification of commercial marketing
- Review the Agency's Paragraph IV Certifications List and Competitive Generic Therapy Approvals List

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

- Address all new, timely filed, later-listed patents and patent information (e.g., use codes) with a patent certification or section viii statement, as applicable
- **New** or **updated**, timely filed patent listings require **new** certifications or statements
- Prior Paragraph IV (PIV) certification for the same patent does not sufficiently address newly listed patent information (e.g., new or revised use codes)

Notice Requirements for PIV Certifications Submitted After Original Submission of ANDA

- Applicants that elect to submit a PIV certification to a timely filed, later-listed patent or use code must comply with the notice requirements under 21 CFR 314.95
  - Includes providing adequate documentation of notice (21 CFR 314.95(e))
- Prior notice sent for PIV certification to the same patent is not sufficient notice for PIV certification to new patent information (e.g., new use code)

New Exclusivities

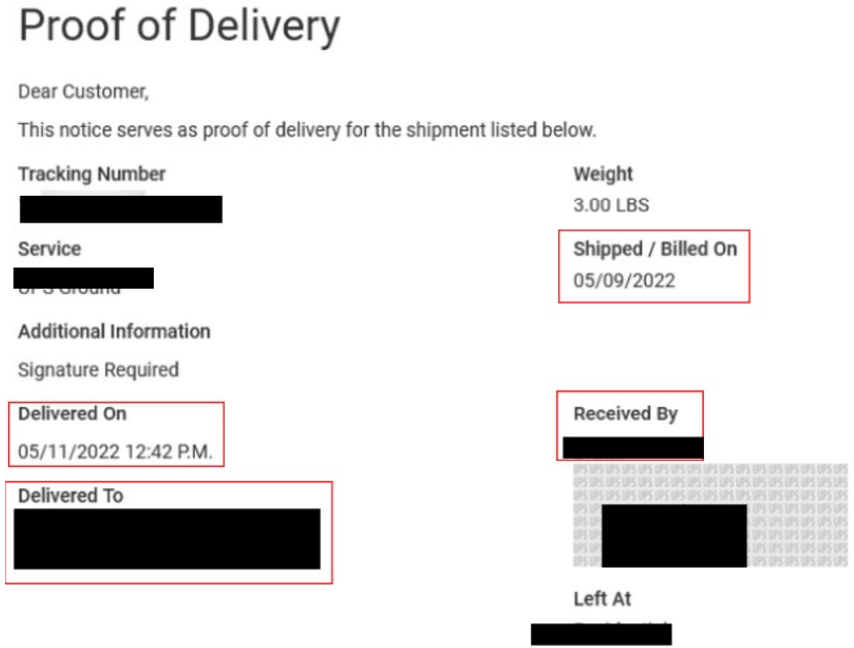
- Update exclusivity statement provided pursuant to 21 CFR 314.94(a)(3) to address new marketing exclusivities recognized for the reference listed drug (RLD) after abbreviated new drug application (ANDA) submission
- Clearly state intent
  - Applicant is not seeking approval of its ANDA prior to exclusivity expiration and is retaining the exclusivity-protected information in its proposed labeling, or
  - Applicant is seeking approval of its ANDA prior to exclusivity expiration and is omitting (i.e., is "carving-out") the exclusivity-protected information from its proposed labeling

Documentation of Timely Sending and Receipt of Notice 21 CFR 314.95(e)

Adequate documentation of notice includes:

- 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
- Documentation of the **date of receipt of notice**
  - **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.

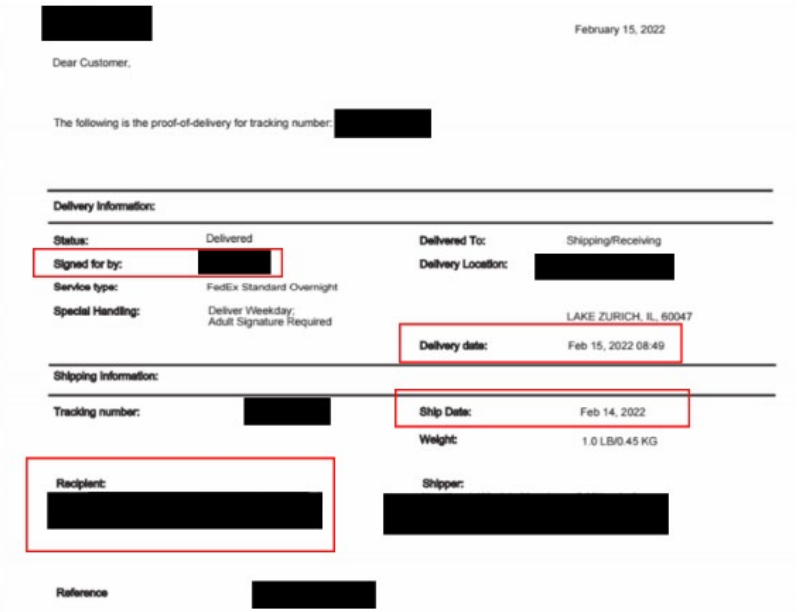
Delivered To
[redacted]

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
Signed for by: [redacted]
Service type: FedEx Standard Overnight
Special Handling: Deliver Weekday; Adult Signature Required

Delivered To: Shipping/Receiving
Delivery Location: [redacted]
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

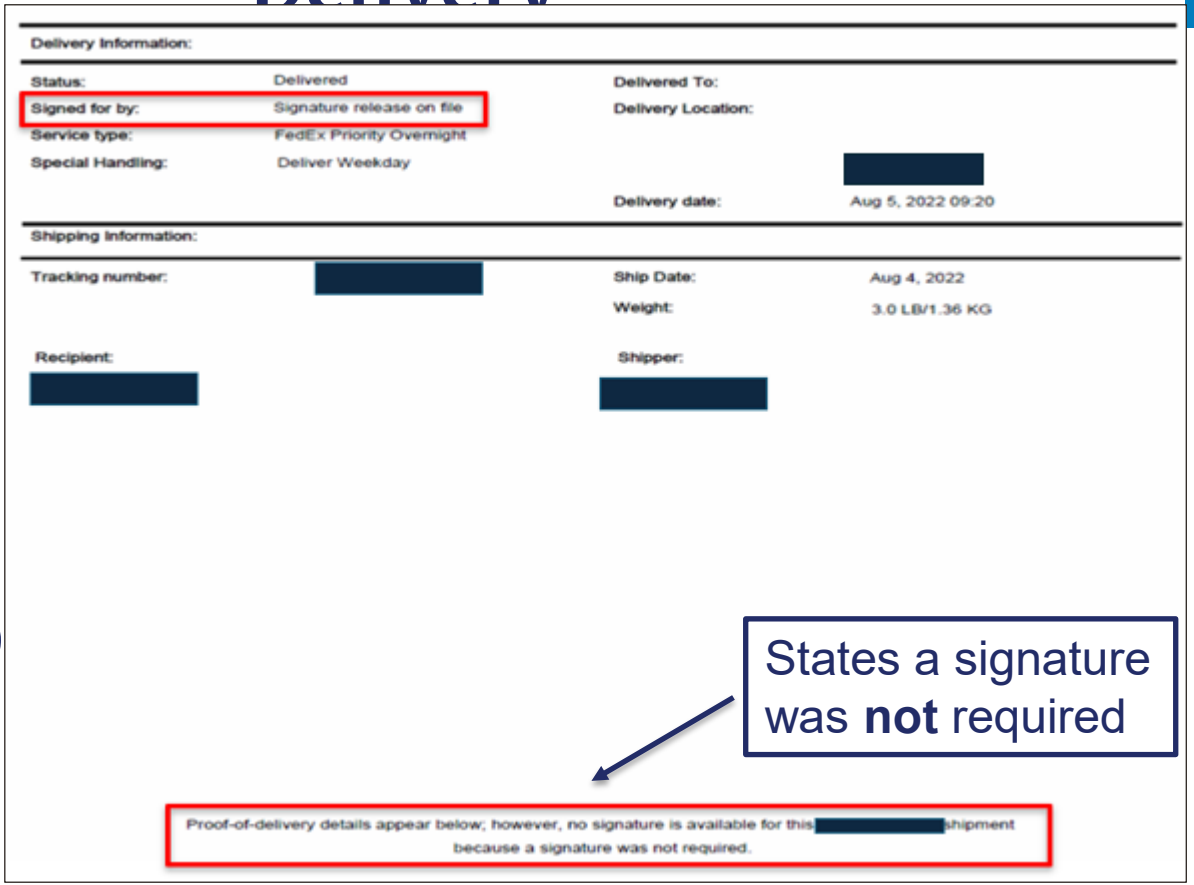
Recipient: [redacted]

Shipper: [redacted]

Reference [redacted]

Inadequate Signature Proof of Delivery

"Signed for by" field does **not** provide a name



Delivery Information:

Status:	Delivered	Delivered To:	
Signed for by:	Signature release on file	Delivery Location:	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday		[redacted]
		Delivery date:	Aug 5, 2022 09:20

Shipping Information:

Tracking number:	[redacted]	Ship Date:	Aug 4, 2022
		Weight:	3.0 LB/1.36 KG
Recipient:	[redacted]	Shipper:	[redacted]

Proof-of-delivery details appear below; however, no signature is available for this [redacted] shipment because a signature was not required.

States a signature was **not** required

This delivery receipt does **not** comply with 21 CFR 314.95(e)

Challenge Question #1

An applicant provided a PIV certification to the ’123 method-of-use patent and associated U-456 use code in its original submission. A new, timely filed use code, U-789, is subsequently listed for the ’123 patent.

True or False: The applicant must address the later-listed U-789 use code with a patent certification or a section viii statement.

Answer: True

Notification of Filing of Legal Action

- Notify FDA within 14 days of the filing of any legal action filed within 45 days of receipt of the notice pursuant to 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
- 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 (21 CFR 314.107(b)(1)(i)(C))

Notification of Court Actions and Licensing Agreements

- Notify FDA of the entry of all final court orders or judgments within 14 days pursuant to 21 CFR 314.107(e)
- Applicants that have been granted a licensing agreement must submit a statement pursuant to 21 CFR 314.94(a)(12)(v)

Pediatric Exclusivity

- Additional 6 months of exclusivity added to the end of certain listed patents and/or exclusivity (section 505A of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
  - IS an extension of the marketing exclusivity
    - Applicants may “carve out” protected information for the duration of the exclusivity and 6-month pediatric exclusivity period
  - Is NOT an extension of the patent
    - It is not permissible to submit a section viii statement to “carve out” the 6-month pediatric exclusivity
    - Upon expiration of a patent, the section viii statement is deemed to be a paragraph II certification
    - Once the patent has expired, there is no legal basis to omit information protected by that patent from an ANDA’s proposed labeling

Challenge Question #2

An applicant provided a section viii statement to the ’123 method-of-use patent and associated U-456 use code and submitted labeling omitting the protected information. The patent expired on April 1, 2026, with pediatric exclusivity that expires on October 1, 2026. Which of the following is NOT true following expiration of the patent on April 1, 2026?

A. The section viii statement is deemed to be a PII certification.

B. The applicant can maintain its labeling “carve-out” of the information covered by the expired ’123 patent and U-456 use code.

C. The applicant must revise its labeling to add back the information covered by the expired ’123 patent and U-456 use code.

Notification of Commercial Marketing

180-day Patent Challenge (PC) Exclusivity

- A “first applicant” may be eligible for 180-day PC exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act
  - Must notify FDA within 30 days of commercial marketing pursuant to 21 CFR 314.107(c)(2)

180-day Competitive Generic Therapy (CGT) Exclusivity

- The “first approved applicant” for a drug designated as a CGT under section 505(j)(5)(B)(v) may be eligible for CGT 180-day exclusivity
  - This exclusivity does not block approval of other applicants until the first approved applicant commences marketing
  - First approved applicants must commercially market within 75 days after date of approval as described in section 505(j)(5)(D)(iv). If not, the exclusivity is forfeited
  - FDA recommends that first approved applicants notify FDA the same day they commence commercial marketing

Important Public Resources: Paragraph IV Certifications List

Paragraph IV Patent Certifications
February 2, 2026

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Abacavir Sulfate	Tablets	300 mg	Ziagen 20977	1/28/2009	1	Eligible	2/11/2020	6/18/2012	6/19/2012	5/14/2018
Abacavir	Oral Solution	20 mg/mL	Ziagen 20978	12/27/2012	1	Eligible	2/11/2020	9/26/2016	9/15/2017	5/14/2018
Abacavir Sulfate, Dolutegravir and Lamivudine	Tablets	600 mg/50 mg/ 300 mg	Triumeq 205551	8/14/2017	5					12/8/2029
Abacavir Sulfate, Dolutegravir and Lamivudine	Tablets for Oral Suspension	60 mg/5 mg/30 mg	Triumeq PD 215413	3/31/2023	1					12/8/2029
Abacavir Sulfate and Lamivudine	Tablets	600 mg/300 mg	Epzicom 21652	9/27/2007	1	Eligible	2/11/2020	9/29/2016	9/29/2016	5/14/2018
Abacavir Sulfate, Lamivudine and Zidovudine	Tablets	300 mg/150 mg/ 300 mg	Trizivir 21205	3/22/2011	1	Eligible	2/11/2020	12/5/2013	12/17/2013	5/14/2018
Abaloparatide	Subcutaneous Injection	3.12 mg/1.56 mL	Tymlos 208743	6/21/2022	1					1/10/2040
Abiraterone Acetate	Tablets	125 mg	Yonsa 210308	7/23/2018	1	Deferred	7/25/2022	6/24/2022		3/17/2034

Found on FDA's Patent Certifications and Suitability Petitions | FDA website

Important Public Resources: CGT Approvals List

CGT Approvals List

Search:

Export Excel Show 25 entries

No.	RLD & NDA No.	ANDA No.	ANDA Applicant	Active Ingredient, Form, Strength	Approval Date	CGT Eligible	CGT Forfeiture	First Marketing Date
473	Briviact NDA 205838	220164	Lupin Inc.	Brivaracetam Oral Solution, 10 mg/mL	2/23/2026	No	N/A	N/A
472	Atrovent HFA NDA 021527	217953	Armstrong Pharmaceuticals, Inc.	Ipratropium Bromide HFA Inhalation Aerosol, 21 mcg/inhalation (17 mcg/actuation)	2/23/2026	No	N/A	N/A

Found on FDA's Competitive Generic Therapy Approvals | FDA website

Summary

- Address all new, timely filed, later-listed patents and use codes. Applicants that elect to submit a PIV certification must comply with the notice requirements under 21 CFR 314.95
- Update exclusivity statement to address new marketing exclusivities
- Provide notification of filing of legal action and outcome of litigation in compliance with the applicable requirements under 21 CFR 314.107
- Submit a statement pursuant to 21 CFR 314.94(a)(12)(v) if granted a licensing agreement
- Pediatric exclusivity is not an extension of a patent and cannot be “carved-out”
- Timely notify FDA of commercial marketing of exclusivity-eligible ANDAs
- Utilize the PIV Certifications List and CGT Approvals List