Overview: The CREATES Act and Covered Product Authorizations

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Learning Objectives

- Understand what the CREATES Act is and how it works
- Learn how to obtain a covered product authorization under CREATES from FDA

Note

While this presentation is focused on the generic industry, the pathway established in the CREATES Act is available for developers of generic, 505(b)(2) and biosimilar applications seeking samples to support their applications.

What was CREATES trying to fix?

Samples Access Problem: in a nutshell

- Generic company needs to show bioequivalence (BE)
- Usually requires BE studies comparing to reference listed drug (RLD)
- Typically, RLD can be obtained via normal distribution channels, but sometimes distribution limitations are in place

Samples Access Problem: in a nutshell

- Distribution limitations can be imposed:
  - Voluntarily by brand company, or
  - In connection with FDA-required Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use (ETASU)

Once distribution limitations are in place…

Reports that some brands:

- Argued REMS prohibited RLD sale (or they had no obligation to sell RLD)
- Imposed conditions on sale of RLD that generic companies argued were difficult/impossible to comply with OR
- Placed restrictions in their agreements with wholesalers/third parties limiting their ability to sell RLD to competitors

Upshot

Protracted and/or unsuccessful efforts to obtain RLD slowed, prevented or deterred generic development of these products

Creating and Restoring Equal Access to Equivalent Samples

- Private right of action
  - Specific steps for brand & generic to follow in transaction for samples
- Injunctive relief ordering sample sale
- Attorneys fees for generic
- High monetary award to deter withholding of samples

The CREATES Act: Resources

- FDA web page: "Access to Product Samples: The CREATES Act"
  - Information re: the CREATES Act
  - Link to the **full text of the law**
  - Link to **FDA guidance** on how to obtain a covered product authorization under CREATES
- Web page available using this link

The Civil Action

- Eligible product developer (generic) can bring suit in an appropriate US district court
- alleging that the license holder (brand) has declined to provide them with
  - sufficient quantities of the covered product
  - on commercially reasonable, market based terms.

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Definitions

Sufficient quantities:

An amount of a covered product that the developer determines allows it to conduct testing/fulfill regulatory requirements to support its application

Definitions

Commercially reasonable, market based terms:

- a nondiscriminatory price for the sale of the covered product at or below the most recent wholesale acquisition cost for the drug,

Definitions

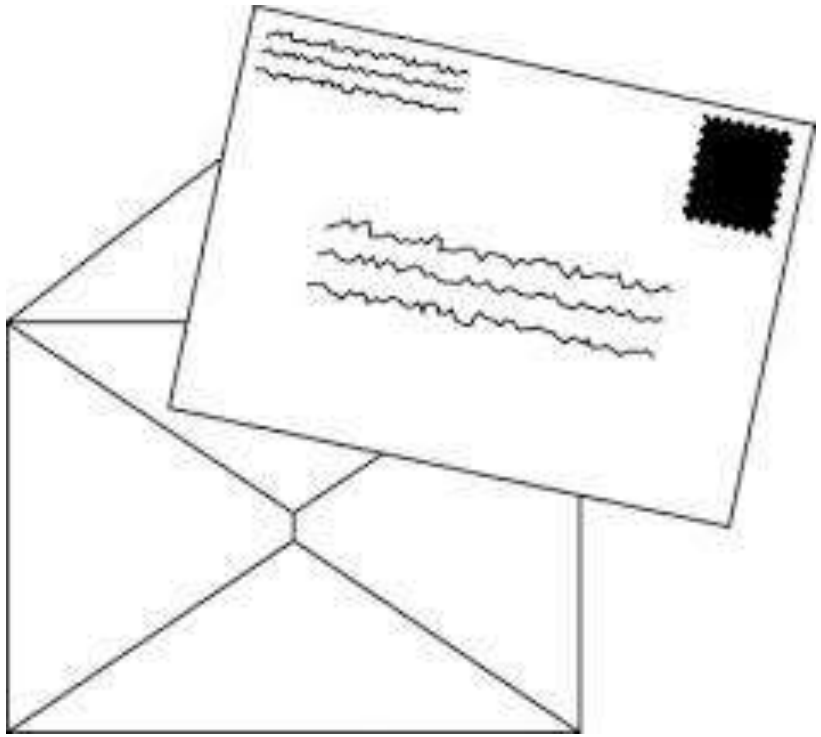
Commercially reasonable, market based terms

- a schedule for delivery that results in transfer of the covered product to the generic consistent with the timing set out in the statute; and

Definitions

Commercially reasonable, market based terms

- no additional conditions are imposed on the sale of the covered product



ELEMENTS

Generic must prove that:

It submitted a written request to the brand to purchase sufficient quantities of the covered product, and the request:

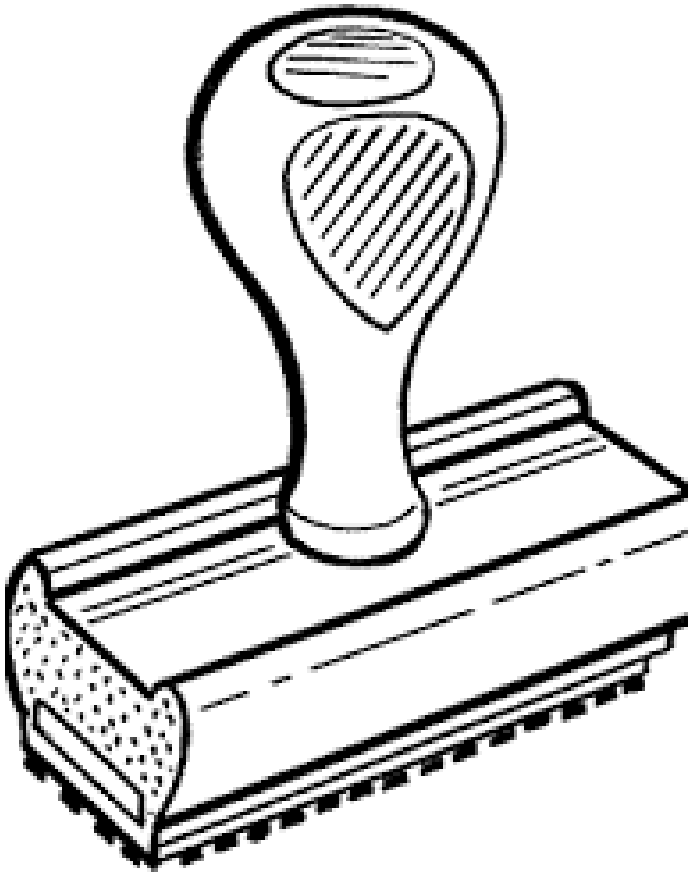
- was sent to a named corporate officer of the brand
- was made by certified/registered mail w/return receipt requested
- specified a generic point of contact and means for written and electronic communication with them, and
- provided a delivery address for samples

ELEMENTS (cont.)

Generic must prove that:

The brand did not deliver sufficient quantities on commercially reasonable, market-based terms within **31 days**:

- of receiving the request (for non-REMS ETASU products)
- of receiving either the request OR the covered product authorization, whichever is later (for REMS ETASU products)



Covered Product Authorization

Required if you want to use the CREATES pathway for a REMS ETASU product

- Must request CPA from FDA
- FDA must respond within 120 days
- FDA has issued draft guidance on how to obtain a CPA
- More on this later

Affirmative Defenses

Brand must prove:

1. No access to the product
2. No restrictions on third party sellers and RLD available to the generic through them, **OR**
3. Generic company didn't respond in time

Affirmative Defense 1

No access to the product

On the date the request was made:

- Neither the brand nor any of its agents, wholesalers, or distributors **was engaged in the manufacturing or commercial marketing** of the covered product; AND
- Neither the brand nor any of its agents, wholesalers, or distributors otherwise **had access to inventory** of the covered product to supply it to the generic on commercially reasonable, market-based terms

Affirmative Defense 2

No restrictions on third party sellers and product is available to the generic through them

- The brand sells the covered product through agents, distributors, or wholesalers and has placed no restrictions, explicit or implicit, on its agents, distributors or wholesalers to sell covered product to product developers, AND
- the covered product can be purchased by the generic in sufficient quantities on commercially reasonable market-based terms from them.

Affirmative Defense 3

The generic didn't respond in time

The brand made an offer to the specified person via the specified method to sell sufficient quantities on commercially reasonable, market based terms

- within 14 days of receiving the request and the generic didn't respond to it within 7 days

  (for a non-REMS ETASU product)

- within 20 days of receiving the request/CPA and the generic didn't respond to the offer within 10 days

  (for a REMS ETASU product)

The CREATES process

Non-REMS ETASU products

1. **Generic** sends written request for samples
2. **Brand** responds within 14 days with an offer to sell
3. **Generic** responds to offer within 7 days
4. **Brand** must provide samples within 31 days of original request

1. **Generic** submits request for covered product authorization (CPA) to FDA
2. **FDA** responds within 120 days. If granted…
3. **Generic** sends CPA to brand company with request for samples
4. **Brand** responds within 20 days with an offer to sell
5. **Generic** responds to offer within 10 days
6. **Brand** must provide samples within 31 days of original request/CPA

The CREATES process

REMS ETASU products

Remedies

If generic prevails in civil action, court shall:

1. Order brand to provide generic with sufficient quantities of covered product without delay on commercially reasonable, market-based terms

Remedies (cont.)

2. Award generic reasonable attorneys fees and costs of the civil action

Remedies (cont.)

3. Award to generic a **monetary amount sufficient to deter** brand from failing to provide developers with sufficient quantities of covered products on commercially reasonable, market based terms, if court finds that brand delayed providing sufficient quantities without a legitimate business justification OR failed to comply with an order under (1)

Remedies (cont.)

Monetary award capped at **revenues earned on product** during period between 31 days after brand receipt of request for samples/CPA and generic receipt of sufficient quantities of product

Avoidance of delay

Court can order brand to sell samples to generic without delay before determining availability/level of monetary award

The CREATES process

REMS ETASU products

1. **Generic** submits request for covered product authorization (CPA) to FDA
2. **FDA** responds within 120 days. If granted…
3. **Generic** sends CPA to brand company with request for samples*
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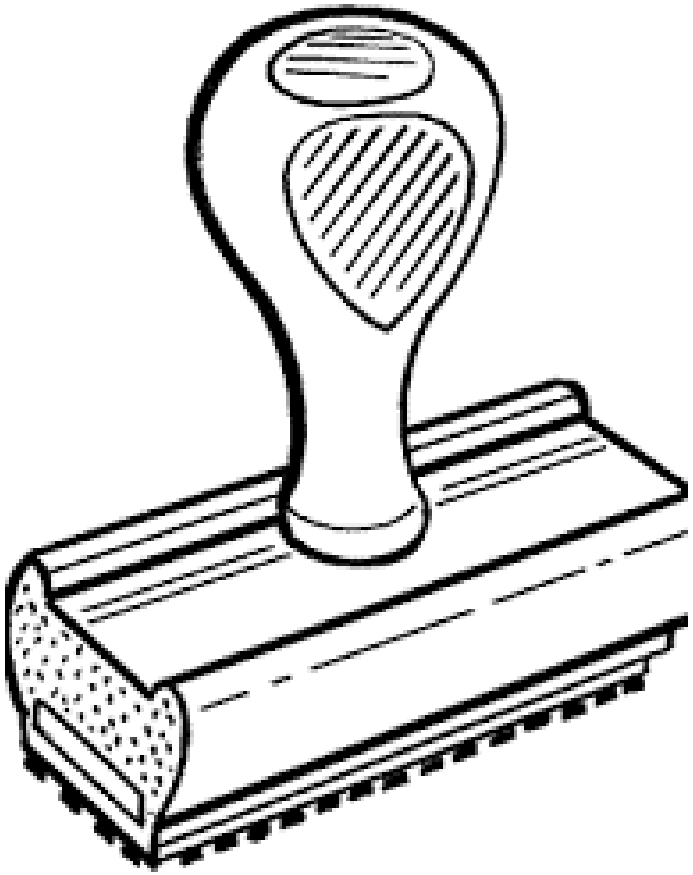
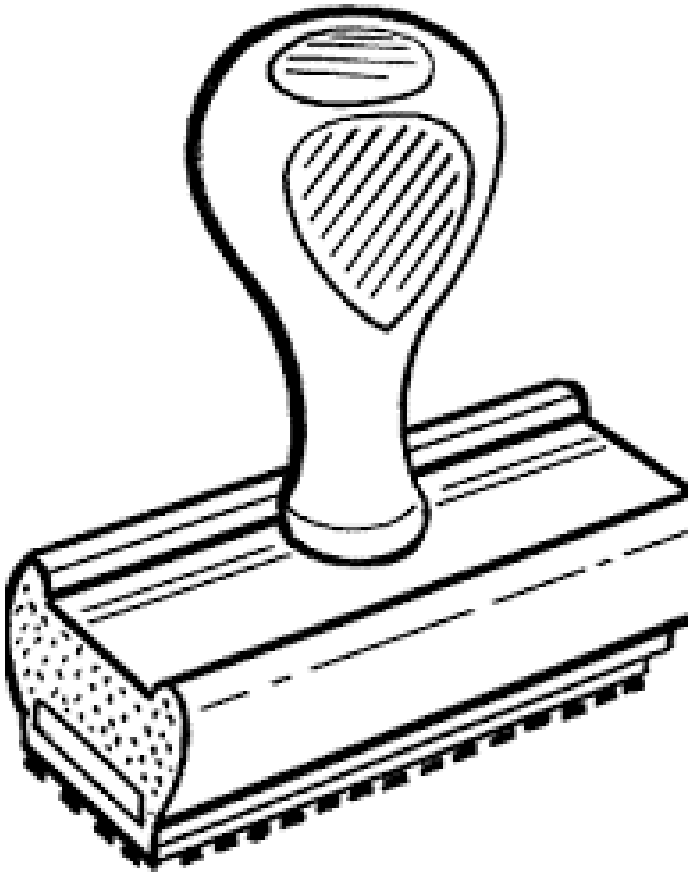


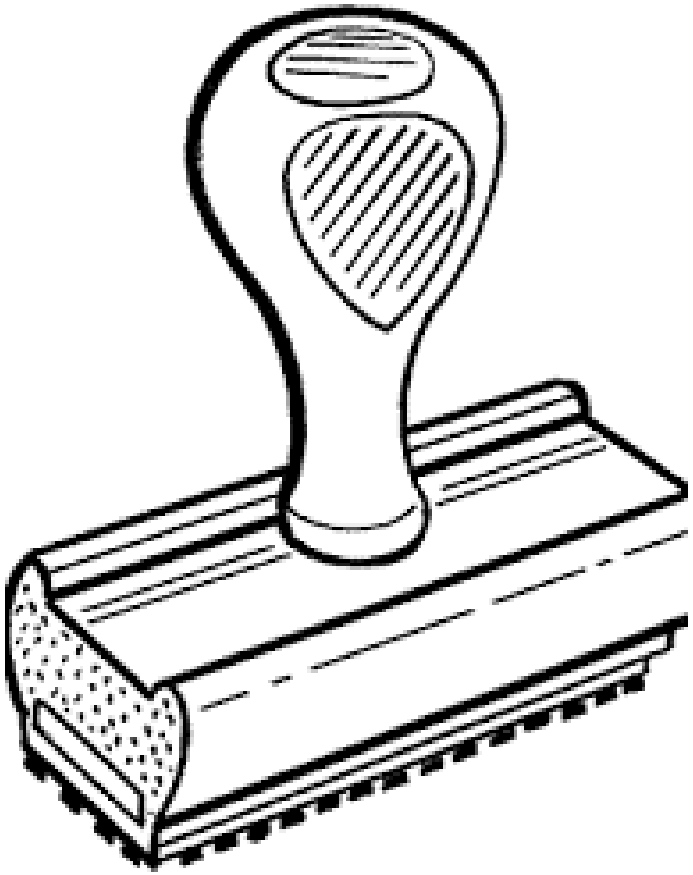
Covered Product Authorization (CPA)

- Required if you want to use the CREATES pathway for a REMS ETASU product
- FDA has issued draft guidance on how to obtain a CPA
  - available at: https://www.fda.gov/media/161730/download



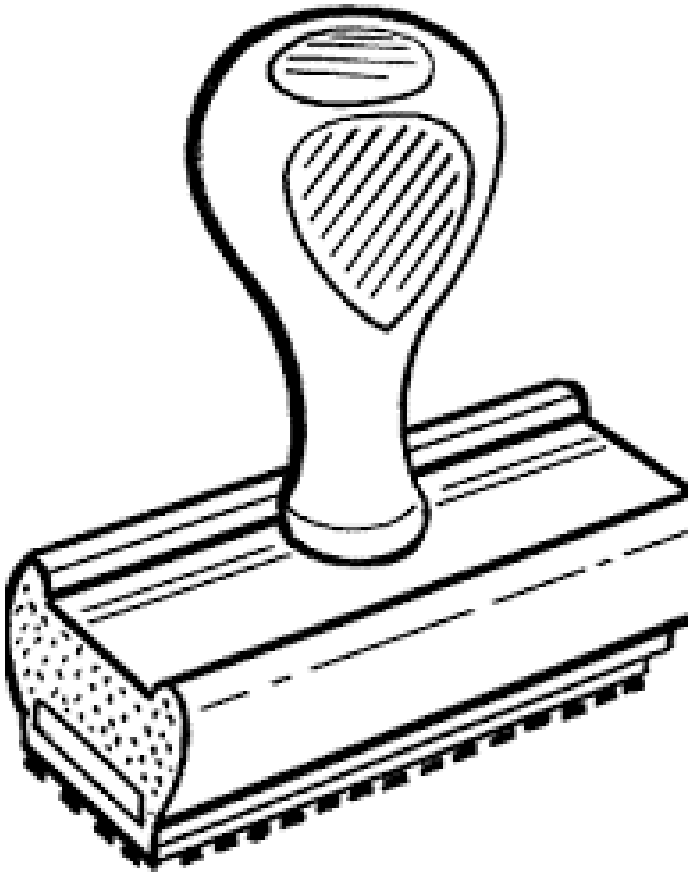
CPAs are only for REMS ETASU products

- To prevail in the private right of action established by CREATES, a developer seeking samples of a product *not* subject to an ETASU REMS **<u>does not need a CPA</u>**



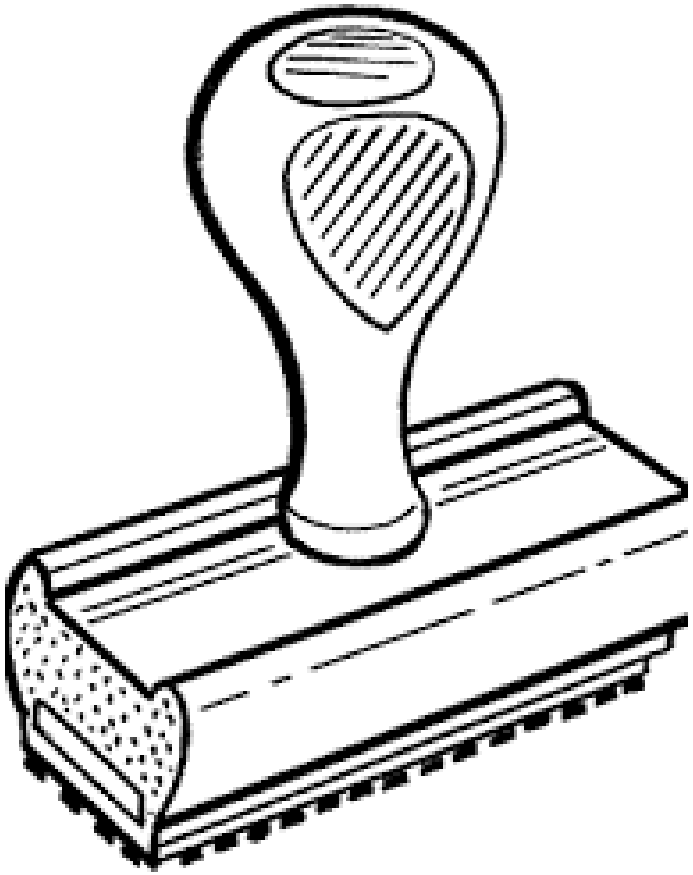
CPAs are only for REMS ETASU products

- Check whether product has a REMS ETASU before requesting a CPA
  - FDA's online listing of approved REMS is available at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm



How to obtain a CPA

- For generic products, submit the CPA request as a controlled correspondence to the CDER NextGen Collaboration Portal
- Prominently identify the request as a “REQUEST FOR COVERED PRODUCT AUTHORIZATION”
- General questions can be submitted to GenericDrugs@fda.hhs.gov

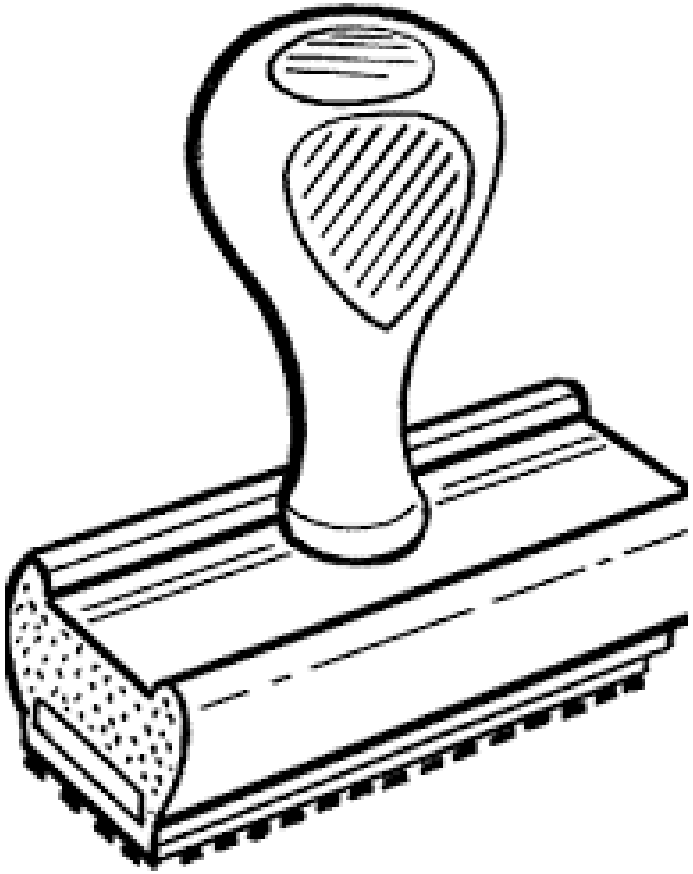


CPAs -- development involving human clinical trials

Include w/the request:

- study protocols
- informed consent documents, and
- informational materials for testing

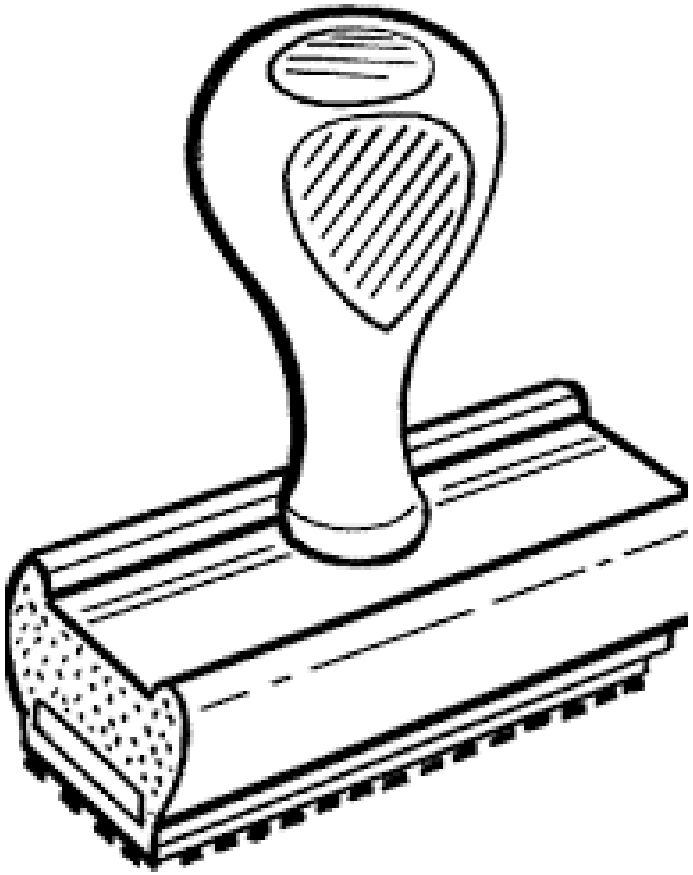
showing that safety protections comparable to those in the REMS for the brand product will be provided for in the study/studies for which samples are sought



CPAs -- development not involving human clinical trials

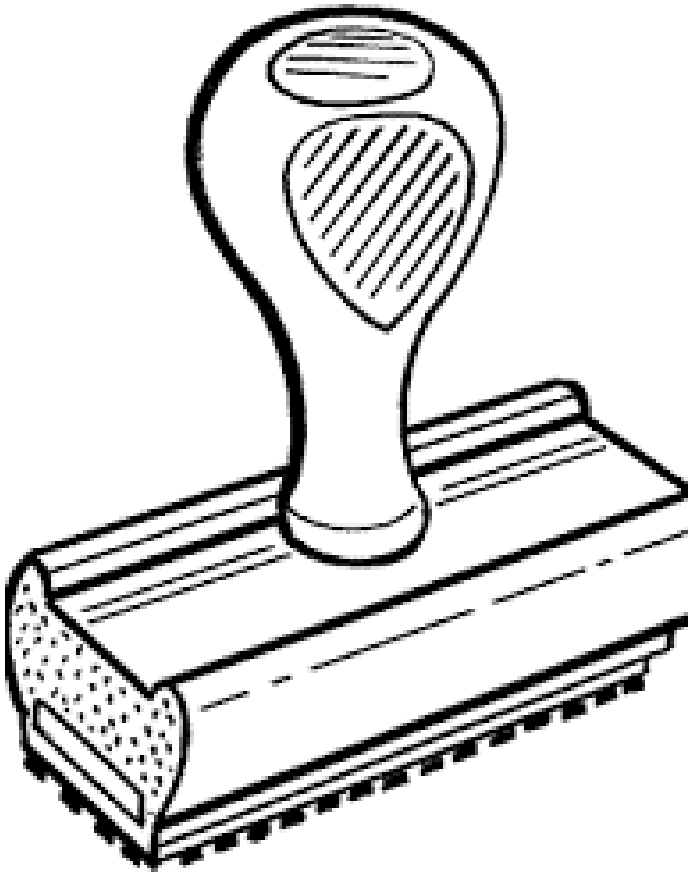
CPA request should state that the samples will not be used for testing in humans

- Plans change?
  - if you receive a CPA for development and testing that does not involve testing in humans and your development plan subsequently changes such that samples are needed for human clinical trials, obtain a new CPA for these purposes



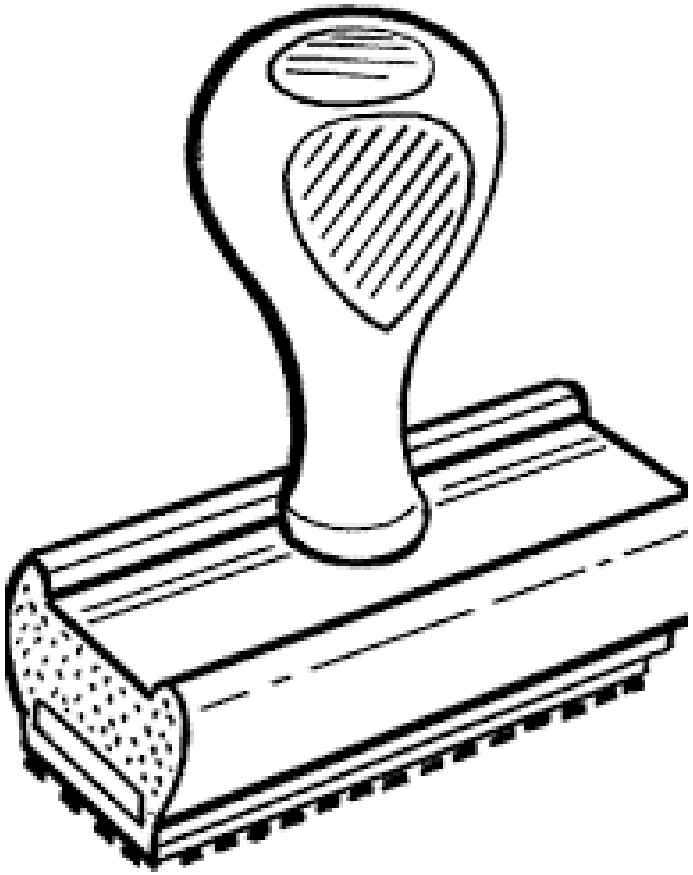
CPA processing & determination

As FDA processes CPA request, we may ask for additional information via an information request (IR)



CPA processing & determination

If FDA determines that the protocols, informed consent documents, and informational materials for testing contain safety protections comparable to those provided by the applicable REMS with ETASU, FDA will issue a CPA within 120 days of the date of request

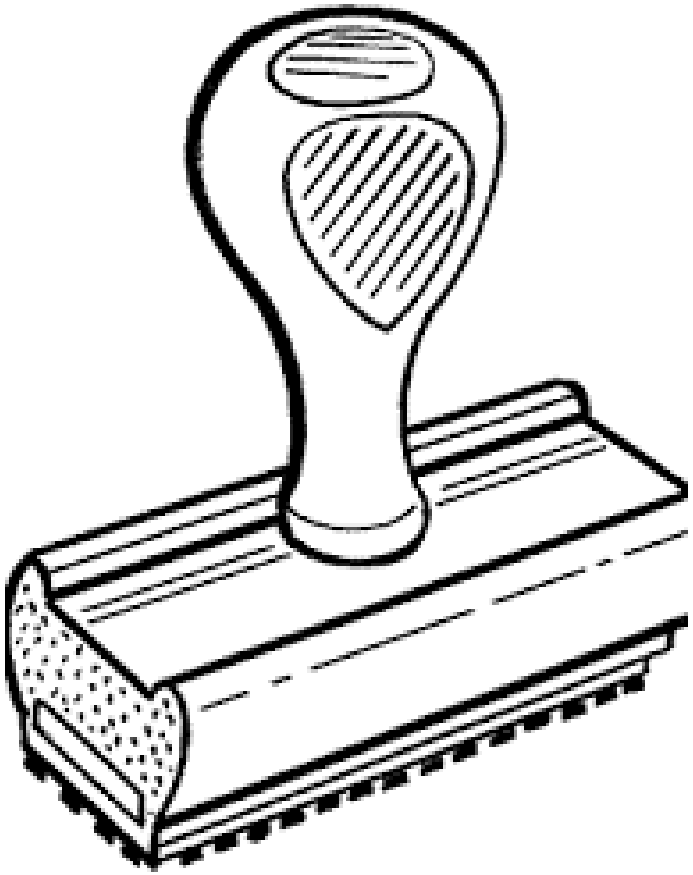


CPA processing & determination

If FDA cannot determine from the materials submitted that safety protections comparable to those in the REMS with ETASU will be provided

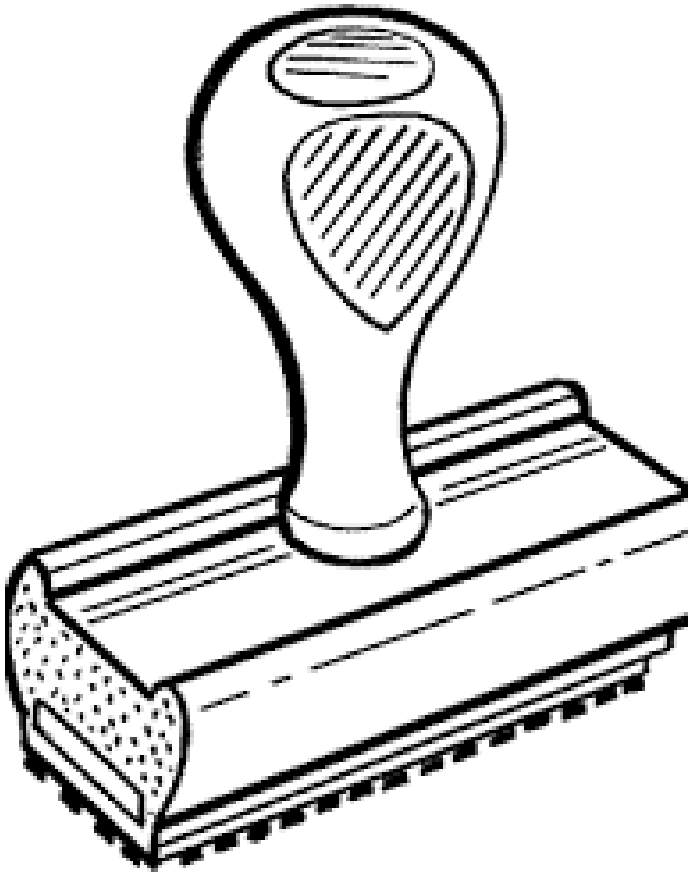
AND

the deficiencies are more significant than can be resolved via an IR, CPA request will be rejected.



CPA processing & determination

CPA resubmissions on new 120-day clock



CPAs -- products on shortage list

- If you seek a CPA for a product on the drug shortage list in effect under FD&C Act section 506E, specify in your request that the product is on the drug shortage list
- See FDA's draft guidance *How to Obtain a CPA* for additional information relevant to those seeking CPAs for products on the drug shortage list

Challenge Question

Generic company X wants to obtain samples of a covered product, so they submit a request for a covered product authorization to FDA. They include study protocols, informed consent documents, and informational materials for testing. Will they receive a CPA?

Answer

It depends!

1. Is the product subject to a REMS with ETASU?
2. Did their materials show that safety protections comparable to those in the REMS for the RLD will be provided?
3. Did they adequately address any information requests from FDA?

The CREATES Act: Resources

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  - Link to the **full text of the law**
  - Link to **FDA guidance** on how to obtain a covered product authorization under CREATES
- Web page available at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act on the CREATES Act