

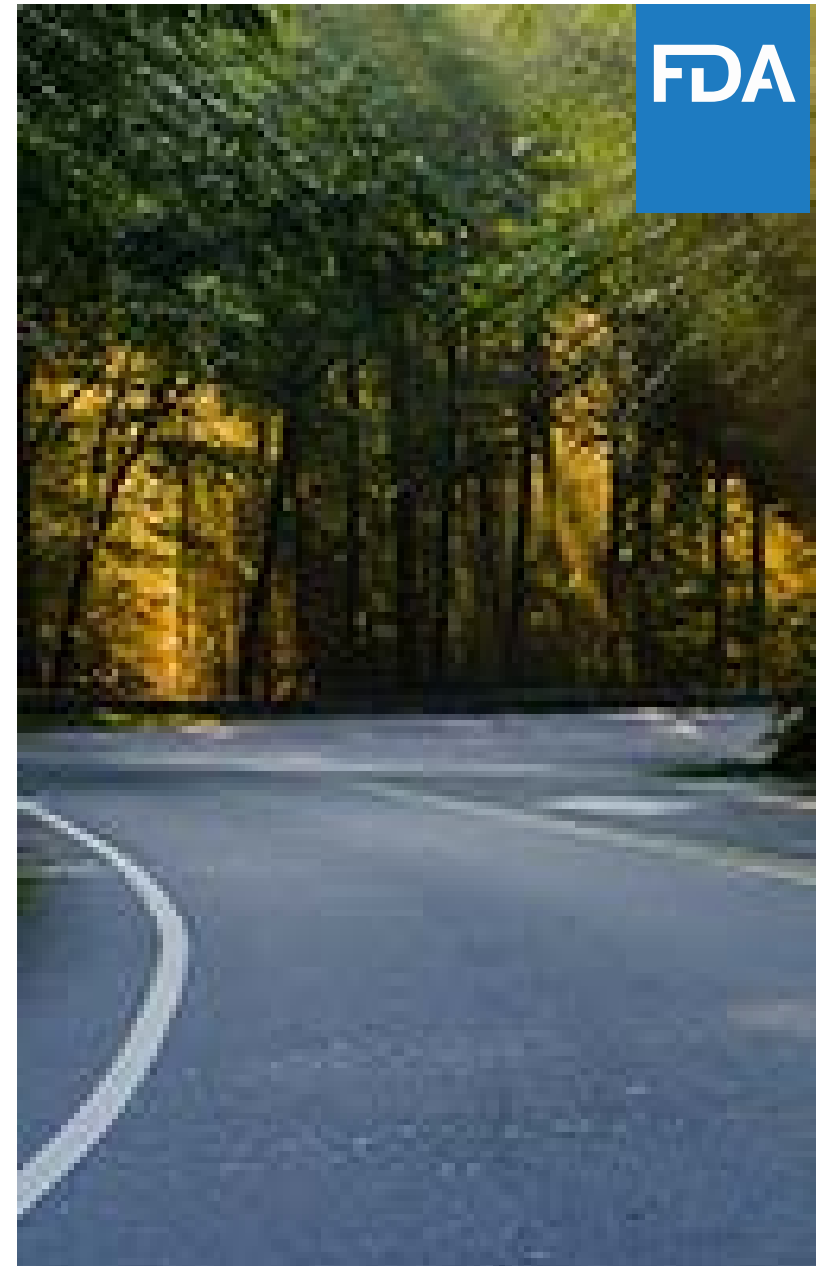
TRANSFER OF OWNERSHIP

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AGENDA

- Program Overview
- Key Terms
- Transfer of Ownership Process
- Submitting a Request
- Transfer Acknowledgement



PROGRAM OVERVIEW

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Transfer of ownership is a program within CTP in which an applicant transfers the rights and responsibilities for their applications to another company. An applicant typically transfers ownership of their applications if they are selling all or part of their company, merging with another company, or both.

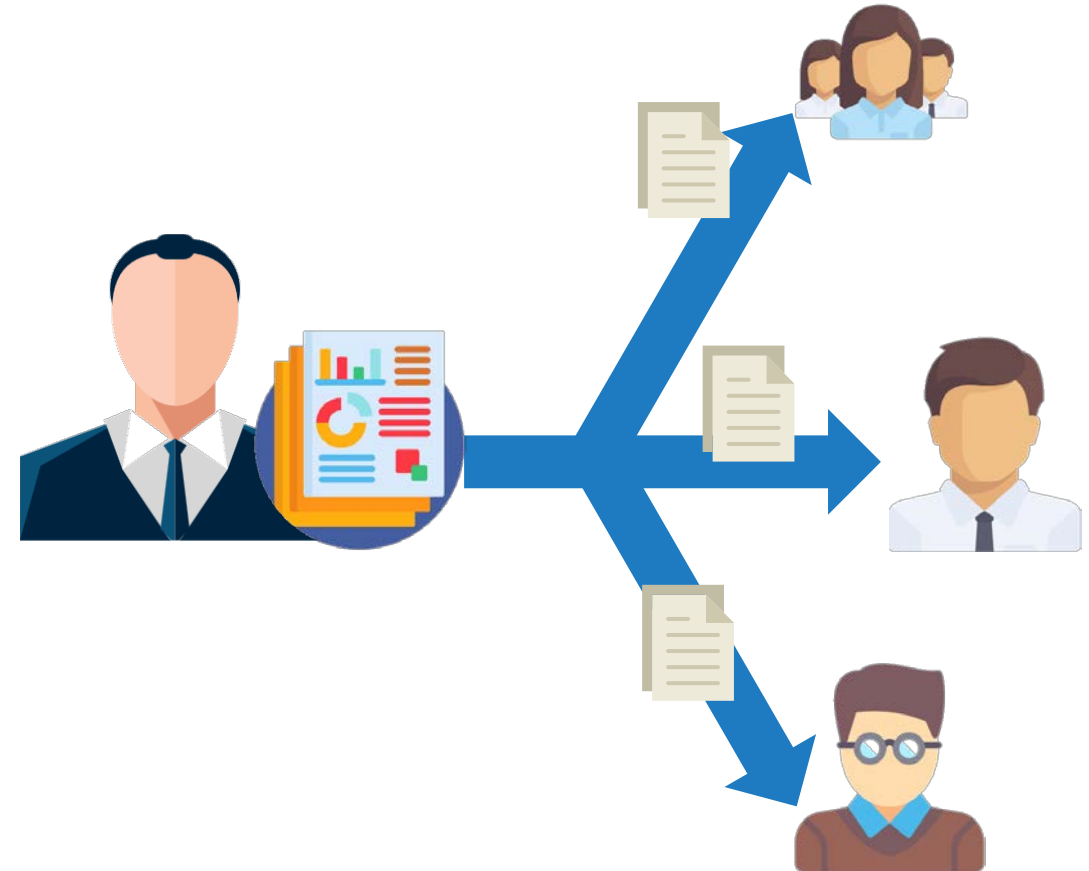


COMMON TRANSFERS

One-to-One Transfer



One-to-Many Transfer



KEY TERMS TO ASSIST WITH THE TRANSFER OF OWNERSHIP PROCESS

Current Applicant

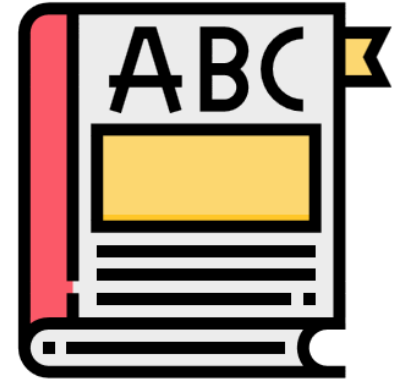
- the entity listed as the applicant of record for the applications
- originator of the transfer request

New Applicant

- the entity assuming ownership of the applications and responsibilities thereafter from the current applicant

Transfer of Ownership Request

- a signed letter from an Authorized representative that contains the information for CTP to start the transfer review process



TRANSFER OF OWNERSHIP PROCESS

OTHER TYPES OF REQUESTS

A transfer of ownership request is:

- ✓ a submission providing adequate information for CTP to start the transfer review process
- ✓ from the current applicant of record, and clearly states the request is to transfer ownership from the current applicant of record to new applicant

A transfer of ownership request is not a:

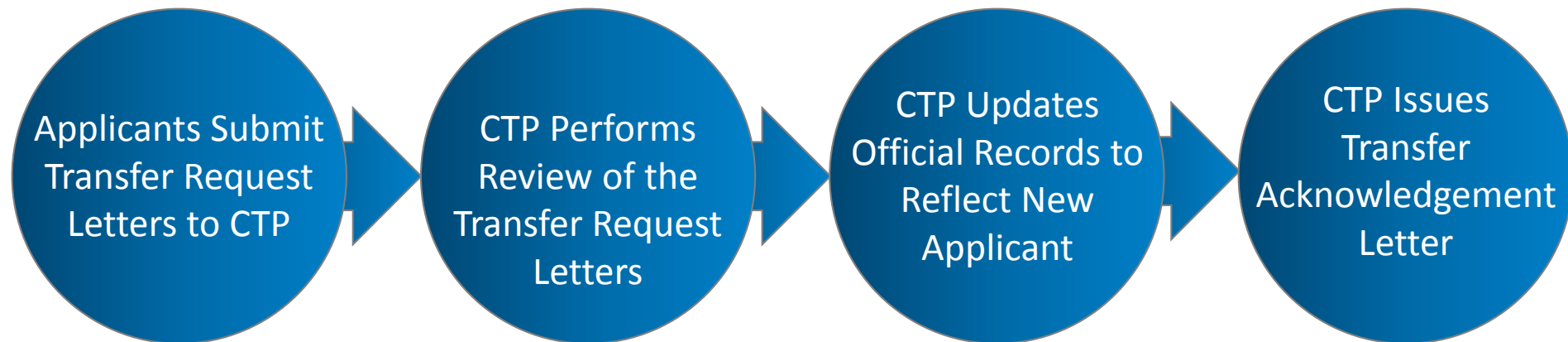
- ✗ Notification of company name change
- ✗ Notice of bankruptcy or sale statement
- ✗ Change in legal representation
- ✗ Change in point of contact
- ✗ Withdrawal Request

TRANSFER OF OWNERSHIP PROCESS

Transfer of Ownership is important to ensure:

- accuracy of all records
- the appropriate individuals are communicating with FDA

Transfer of Ownership Process



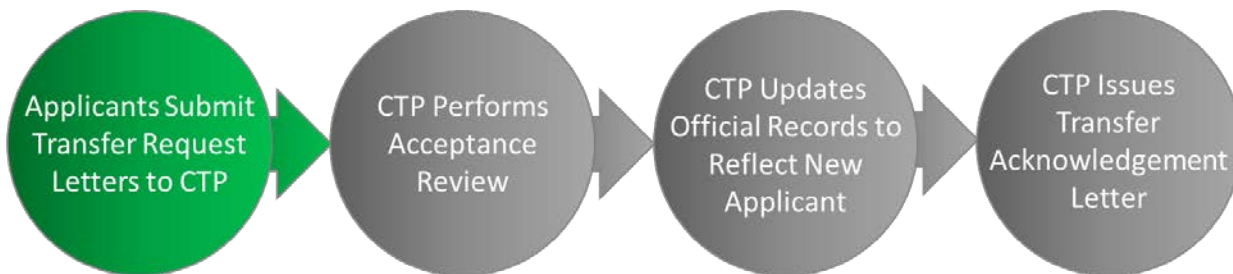
PROCESS FOR CURRENT APPLICANT

Current Applicant

Completes and submits a signed transfer request letter to OS from an Authorized representative that includes:

- ✓ the specific applications and products by STN to be transferred to the new applicant
- ✓ a statement that all rights of the applications have been transferred to the new applicant
- ✓ the name and address of the new applicant
- ✓ the transfer of ownership effective date

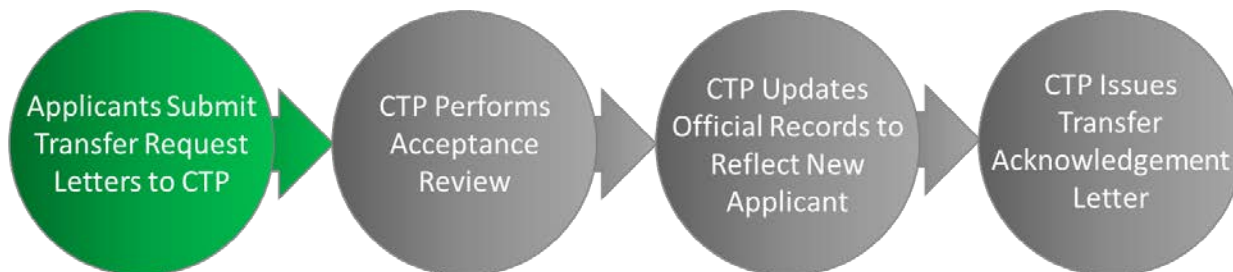
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PROCESS FOR NEW APPLICANT

New Applicant

Completes and submits a signed transfer acceptance letter to OS from an Authorized representative that includes:

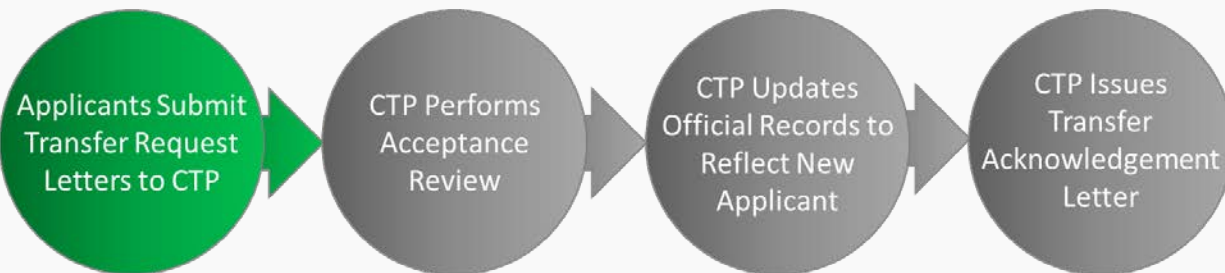
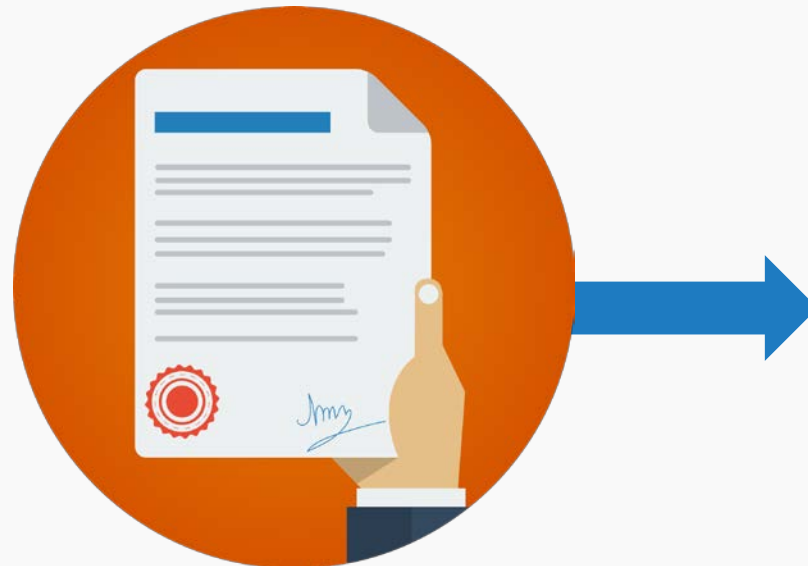


- ✓ the specific applications and product names that are being accepted from current applicant
- ✓ a statement committing to all agreements, promises, and conditions made by current applicant of record contained in the applications
- ✓ a statement that they have a complete copy of the applications, or state they will request a copy
- ✓ a statement that no modifications have been made to the transferred applications
- ✓ the transfer of ownership effective date

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SUBMITTING THE TRANSFER OF OWNERSHIP REQUEST

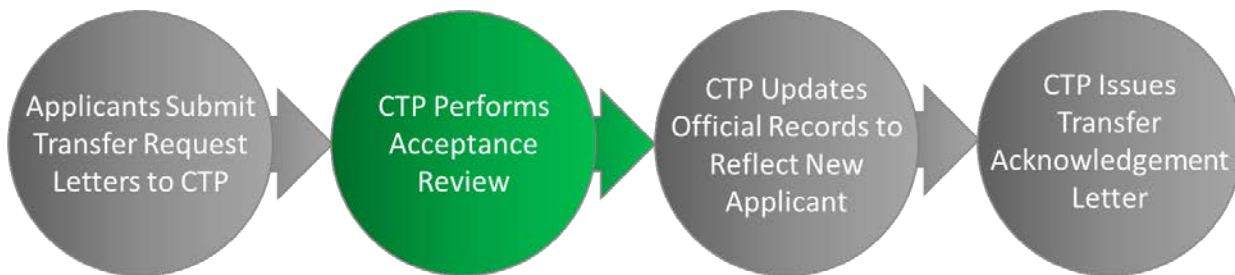
Applicants can submit a transfer of ownership request to CTP using one of the following methods:



CTP REVIEW OF THE REQUEST

CTP will review the transfer request letters for completeness:

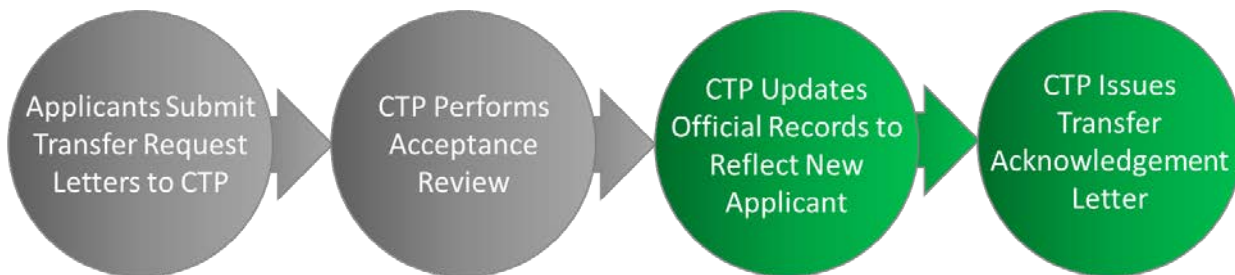
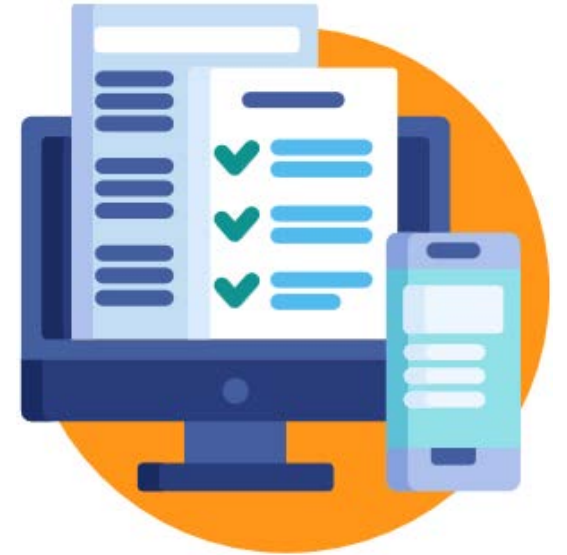
- If the letter is missing information, CTP may reach out to the applicant



TRANSFER ACKNOWLEDGEMENT

Once the transfer of ownership request is complete, CTP has:

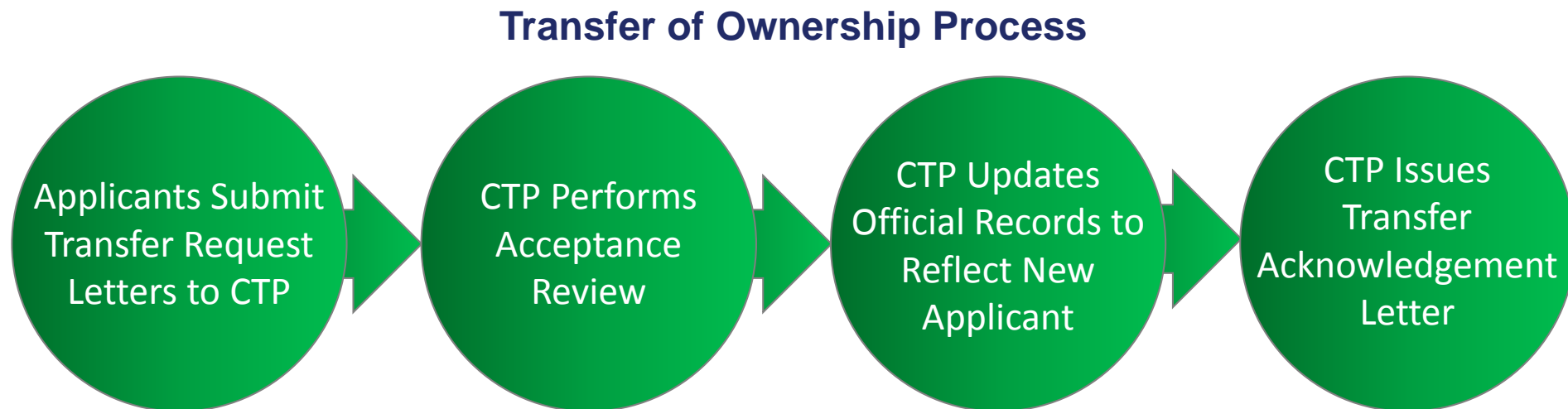
- updated the official records to reflect the new applicant for all applications identified in the transfer request
- issued a transfer acknowledgement letter to the new applicant with a copy to the current applicant



TRANSFER OF OWNERSHIP PROCESS - COMPLETE



With the issuance of the acknowledgement letters, this completes the transfer of ownership process.



END

FDA

Questions?

- Contact your regulatory health project manager
- Contact CTP's Call Center
- Email AskCTP@fda.hhs.gov