U.S. Food and Drug Administration

BECATS External User Guide – Modify a Pharmaceutical Product (CPP) Application Step-by-Step Instructions

February 27, 2023

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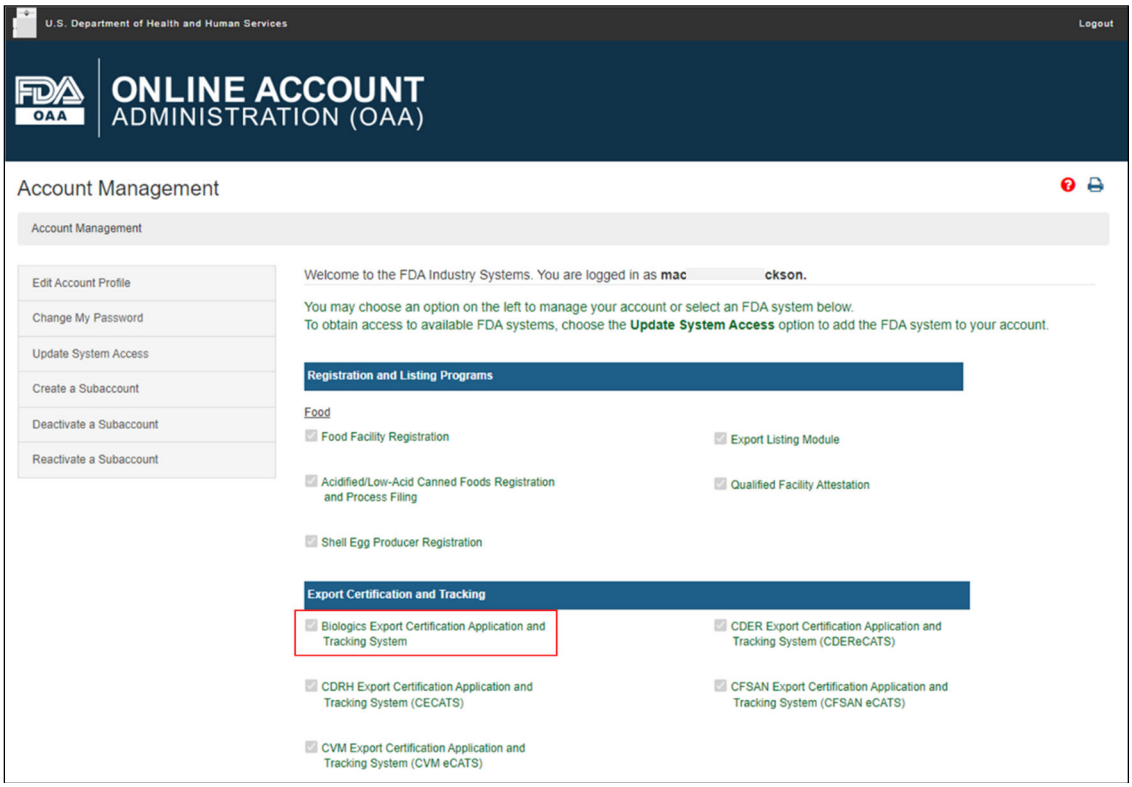
Accessing BECATS

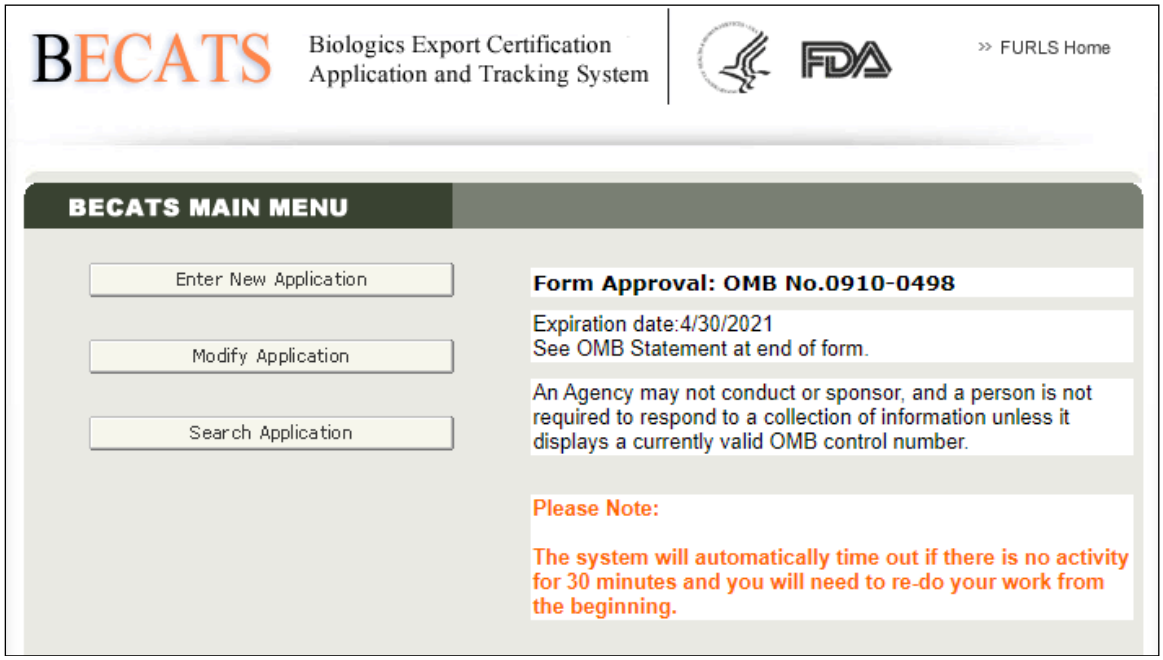
After you have logged into the FDA Industry Systems, select 'Biologics Export Certification Application & Tracking System' (BECATS) from the list of systems available on the FURLS Home Page as shown in **Figure 1** below.

Figure 1: FDA Industry Systems Page



Once you have selected 'Biologics Export Certification Application and Tracking System', the system will direct you to the BECATS Main Menu page. To modify an application, choose 'Modify Application' from the list of options on the BECATS Main Menu Page as shown in **Figure 2** below.

Figure 2: BECATS Main Menu



Modify Application

Based on Notification

The application has been returned for action because there is an issue with the application. You will need to select the 'Modify Application' option from the main menu and then select 'Modify a field or fields based on a notification received' option as shown in **Figure 3** below.

Figure 3: Modify Application Options

The system will display all applications that can be modified as shown in **Figure 4** below.

Figure 4: Display Application that can be Modified

Once you have selected the application to modify, the system will navigate you to the Review Page. There the system will display the application with an 'Edit' button next to each section as shown in **Figure 5** below.

Figure 5: Review Update Page

Get Help

Date: 02/27/2023
Created Date: 02/27/2023 Certificate Type: Certificate of a Pharmaceutical Product (CPP)

REQUESTOR INFORMATION EDIT

Name:Ms. Samantha Lee Firm: ATEK	Address: 1818 Library St Reston, VA 20190 UNITED STATES
Telephone number: 703-1234567 FAX Number:	Email address: phavady.lee@fda.hhs.gov
Firm Tax ID code: 11 - 1111111	Alternate Email Address:

Billing Address
Is the billing address the same as the requester address? Yes No

Account Number:

Delivery Method: Regular Mail | Label File details:

SECTION 1.1 EDIT

Proprietary name: Test Proprietary name
Dosage form: Test Dosage form
Foreign Brand Name: Test foreign brand name

SECTION 1.2, 1.3 & 1.4 EDIT

Active ingredient: Test Active ingredient
Amount per unit dose: Test unit dose

*Restrictions on Sale?
Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization?
Yes No

Product Marketed in Exporting Country
Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority?
Yes No

Test | 1677514624634_searchApplication-flow (4).pdf

SECTION 2A.1 & 2A.2 EDIT

Applicant Address
Is the Applicant Name and Address the same as the Requestor Name and Address? Yes No

Marketing Authorization: STN111111 - 1111 Date of issue: 01/12/2022 Biologics License Number (BLN): 1111

SECTION 2A.3 EDIT

Status of Marketing Authorization Holder(mark appropriate items(s)):
Manufacturer **Packager and /or Relabeler** **Neither**

Marketing Authorization Holder Address
Is the Applicant Name and Address the same as the Requestor Name and Address? Yes No

SECTION 3.1 EDIT

Firm: ATEK **License number (if applicable):**	**Address (P.O. Box not acceptable):** 1818 Library St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Finished Pharmaceutical Product (FPP)	
Date of Last FDA inspection:	**Registration number:** 3000204352
Firm: ATEK 2 **License number (if applicable):**	**Address (P.O. Box not acceptable):** 123 Main St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Bulk Finished Product	
Date of Last FDA inspection:	**Registration number:** 1004782
Firm: ATEK 3 **License number (if applicable):**	**Address (P.O. Box not acceptable):** 1818 Library St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Solvent and Diluents	
Date of Last FDA inspection:	**Registration number:** 1004369

REMARKS EDIT

Do you have any remarks that you want to display on the certificate? Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Remarks Test Rema

IMPORTING COUNTRIES EDIT

ARGENTINA

NUMBER OF CERTIFICATES REQUESTED EDIT

Country Name	Number of Certificates	Additional Certificates
ARGENTINA	1	

Total Fee: $175

EXPORTER'S CERTIFICATION STATEMENT EDIT

Firm Name: ATEK

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplementary Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. All facilities that appear on the certificate are currently registered and each facility has listed each of its products identified for export as required by Section 510 of the Act and 21 CFR Part 207 or 607;
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a Marketing Authorization (Biologics License, NDA, or ANDA);
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613b form;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with Good Manufacturing Practices Regulation for the identified product(s); and
6. Each product(s) identified for export is being exported from the United States

I hereby make this certification of compliance statement for FDA with full knowledge that the making or submission of false statements represent violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

*I Agree Date: 02/27/2023

***Name:** SL ***Title:** Test

Cancel & Start Again | Print Application | Preview Certificate

Submit

Click on the ‘Edit’ button next to the section you would like to modify.

Once you have made the necessary updates to the application and have returned to the final review page, the system will display all sections for your final review.

Once you have submitted the application, the system will display the application number, a message that the application has been successfully updated and send a confirmation email.

Request Additional Certificates

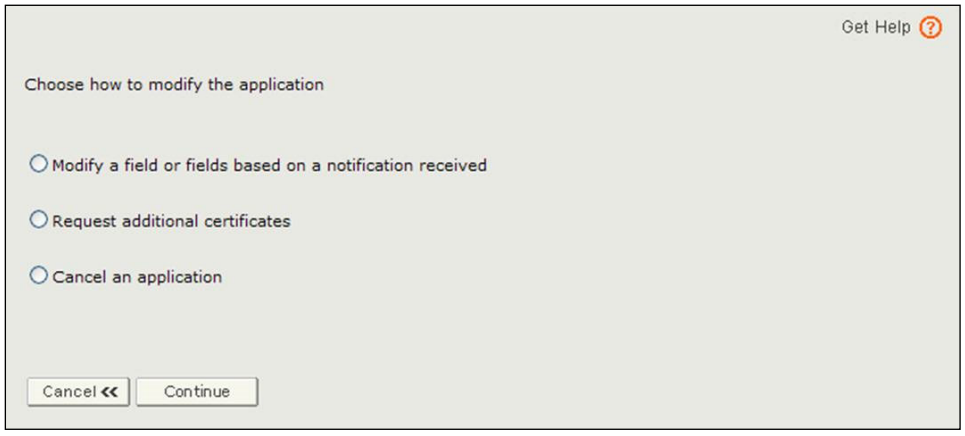
This option allows you to request additional certificates after you have initially submitted the application. The application must be in one of the following states in order to update the number of certificates requested:

- Received
- Ready for Review
- Under Review
- Return for Action

NOTE: Once the application is in a ‘Ready to Print’, ‘Printing in Progress’, or ‘Completed’ status, you will not be able to update the number of certificates requested and you will need to submit a new application.

Select the ‘Modify Application’ option from the main menu. Then select the ‘Request additional certificates’ option as shown in **Figure 6** below.

Figure 6: Request Additional Certificates

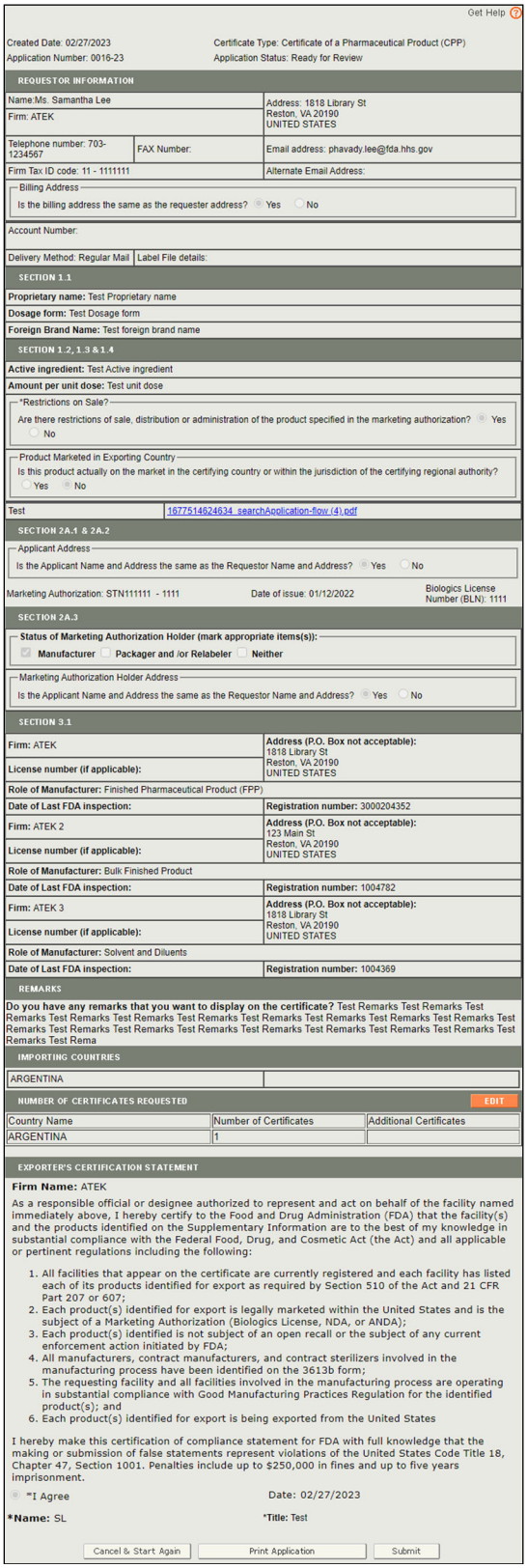


The system will display a list of applications as shown in **Figure 7** below:

Figure 7: Request Additional Certificates Application List

Select the application to request for additional certificates and click on 'Continue'. The system will navigate you to the final review page as shown in **Figure 8** below. The system will display the application with an 'Edit' button next to the Number of Certificates Requested section.

Figure 8: Final Review Page with Edit button for Number of Certificates Requested



Get Help

Created Date: 02/27/2023 | Certificate Type: Certificate of a Pharmaceutical Product (CPP)
Application Number: 0016-23 | Application Status: Ready for Review

REQUESTOR INFORMATION

Name:Ms. Samantha Lee
Firm: ATEK
Address: 1818 Library St
Reston, VA 20190
UNITED STATES
Telephone number: 703-1234567 | FAX Number:
Email address: phavady.lee@fda.hhs.gov
Firm Tax ID code: 11 - 1111111
Alternate Email Address:

Billing Address
Is the billing address the same as the requester address? Yes No

Account Number:

Delivery Method: Regular Mail | Label File details:

SECTION 1.1

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SECTION 1.2, 1.3 & 1.4

Active ingredient: Test Active ingredient
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Test | 1677514624634_searchApplication-flow (4).pdf

SECTION 2A.1 & 2A.2

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Is the Applicant Name and Address the same as the Requestor Name and Address? Yes No

Marketing Authorization: STN111111 - 1111 | Date of issue: 01/12/2022 | Biologics License Number (BLN): 1111

SECTION 2A.3

Status of Marketing Authorization Holder (mark appropriate items(s)):
Manufacturer | Packager and /or Relabeler | Neither

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SECTION 3.1

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Firm: ATEK 2
License number (if applicable):
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Role of Manufacturer: Bulk Finished Product
Date of Last FDA inspection:
Registration number: 1004782

Firm: ATEK 3
License number (if applicable):
Address (P.O. Box not acceptable): 1818 Library St, Reston, VA 20190, UNITED STATES
Role of Manufacturer: Solvent and Diluents
Date of Last FDA inspection:
Registration number: 1004369

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EXPORTER'S CERTIFICATION STATEMENT

Firm Name: ATEK

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1. All facilities that appear on the certificate are currently registered and each facility has listed each of its products identified for export as required by Section 510 of the Act and 21 CFR Part 207 or 607;
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a Marketing Authorization (Biologics License, NDA, or ANDA);
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613b form;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with Good Manufacturing Practices Regulation for the identified product(s); and
6. Each product(s) identified for export is being exported from the United States

I hereby make this certification of compliance statement for FDA with full knowledge that the making or submission of false statements represent violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years imprisonment.

*I Agree | Date: 02/27/2023

***Name:** SL | ***Title:** Test

Cancel & Start Again | Print Application | Submit

Click on the Edit button to navigate to the Number of Certificates Requested section. The system will display the original and additional copies you requested as shown in **Figure 9** below.

Figure 9: Update Number of Certificates Requested

Enter the number of additional copies in the Request Additional Copies field. Once you have entered the number click on 'Continue' to navigate back to the final review page and submit the application.

The system will display the application number, display a message that the application has been successfully updated and send a confirmation email.

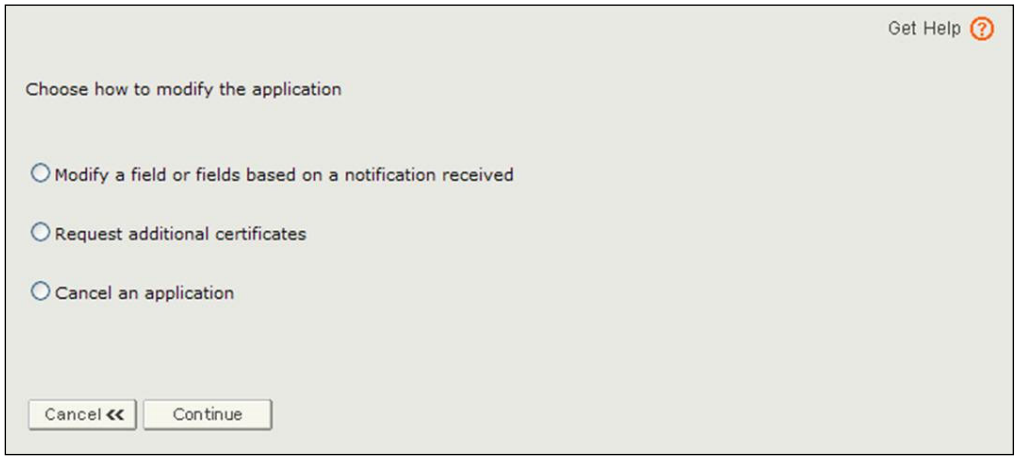
Cancel the Application

This option allows you to cancel an application. You can only cancel application in one of the following statuses:

- Received
- Ready for Review
- Return for Action

Select the Modify Application option from the main menu. You will then need to select the 'Cancel the Application' option as shown in **Figure 10** below.

Figure 10: Cancel the Application



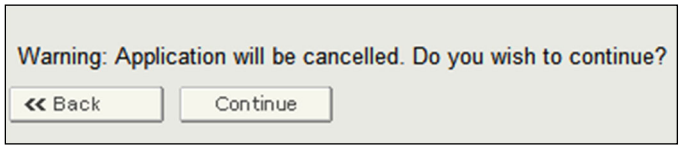
NOTE: If the application is in any other status, you will not be able to cancel the application. Furthermore, you will be responsible for any cost associated to the issuance of the certificate requested. Please contact the FDA at CBERBECATS@fda.hhs.gov if you have any further question.

The system will display all applications that can be cancelled as shown in **Figure 11** below.

Figure 11: Select an Application for Cancellation

Once you have selected the application, the system will provide a warning message prior to cancelling an application as shown in **Figure 12** below.

Figure 12: Cancel the Application Warning



Once confirmed, the system will cancel the application and you will receive an email notification confirming the cancelled application as shown in **Figure 13** below.

Figure 13: Application Successfully Cancelled Message Displayed