

# 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

U.S. Department of Health and Human Services				Logout
ONLINE AC	CCOUNT TON (OAA)			
Account Management				0 🔒
Account Management				
Edit Account Profile Change My Password	Welcome to the FDA Industry Systems. You You may choose an option on the left to ma	anage your account or sele		
Update System Access		, choose the Update Syst	em Access option to add the FDA system to your	account.
Create a Subaccount	Registration and Listing Programs			
Deactivate a Subaccount	Food Food Facility Registration		Export Listing Module	
Reactivate a Subaccount	Acidified/Low-Acid Canned Foods Registration and Process Filing		Qualified Facility Attestation	
	Shell Egg Producer Registration			
	Export Certification and Tracking	с.		
	Biologics Export Certification Application and Tracking System		CDER Export Certification Application and Tracking System (CDEReCATS)	
	CDRH Export Certification Application and Tracking System (CECATS)		CFSAN Export Certification Application and Tracking System (CFSAN eCATS)	
	CVM Export Certification Application and Tracking System (CVM eCATS)			

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

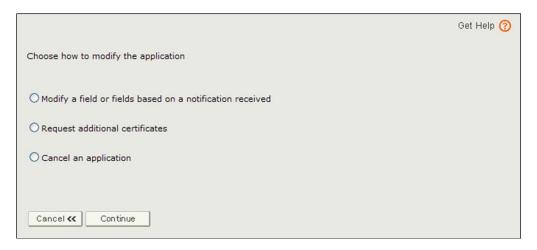
BECATS Biologics Export Application and T	
BECATS MAIN MENU	
Enter New Application	Form Approval: OMB No.0910-0498
Modify Application	Expiration date:4/30/2021 See OMB Statement at end of form.
Search Application	An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.
	Please Note: The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.

# **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

				Get Help	0
Select	Application Number	Date of Application	Certificate Type	Status	
۲	319-9-2012	09/14/2012	Certificate to Foreign Government (CFG)	Return for Action	
	Back Cont	inue			

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: Certific	ate of a Pharmaceutical Product (CPP)
REQUESTOR INFORMATION		
Name:Ms. Samantha Lee		Address: 1818 Library St Reston, VA 20190
Firm: ATEK		UNITED STATES
Telephone number: 703- 1234567	FAX Number:	Email address: phavady.lee@fda.hhs.gov
Firm Tax ID code: 11 - 1111111		Alternate Email Address:
	ne as the requester address?	Yes No
Account Number:		
Delivery Method: Regular Mail	Label File details:	
SECTION 1.1		EDIT
Proprietary name: Test Proprie Dosage form: Test Dosage form		
Foreign Brand Name: Test fore	eign brand name	
SECTION 1.2, 1.3 & 1.4 Active ingredient: Test Active i	ingredient	EDIT
Amount per unit dose: Test ur		
*Restrictions on Sale? Are there restrictions of sale, Yes No	distribution or administration of	of the product specified in the marketing authorization?
Product Marketed in Exportin Is this product actually on the Yes No		y or within the jurisdiction of the certifying regional authority?
Test	1677514624634 sear	chApplication-flow (4).pdf
SECTION 2A.1 & 2A.2		EDIT
Applicant Address	Idress the same as the Reque	stor Name and Address?  Yes No
Marketing Authorization: STN11		
- 1111 SECTION 2A.3	Date of issue: 01/1	2/2022 Biologics License Number (BLN): 1111
	rization Holder(mark approp	
		Neither
Marketing Authorization Hold		star Name and Address? Was his
SECTION 3.1	uness me same as me reque	stor Name and Address? • Yes No
SECTION 3.1		Address (P.O. Box not acceptable):
License number (if applicable	1:	1818 Library St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Finishe		
Date of Last FDA inspection:		Registration number: 3000204352
Firm: ATEK 2		Address (P.O. Box not acceptable): 123 Main St Reston, VA 20190
License number (if applicable		UNITED STATES
Role of Manufacturer: Bulk Fir Date of Last FDA inspection:	hished Product	Registration number: 1004782
Firm: ATEK 3		Address (P.O. Box not acceptable): 1818 Library St
License number (if applicable	):	1818 Library St Reston, VA 20190 UNITED STATES
Role of Manufacturer: Solvent Date of Last FDA inspection:	and Diluents	Registration number: 1004369
REMARKS		EDIT
Remarks Test Remarks Test Re	emarks Test Remarks Test Ren	certificate? Test Remarks Test Remarks Test Remarks Test narks Test Remarks Test Remarks Test Remarks Remarks Test Remarks Test Remarks Test Rema
ARGENTINA		
NUMBER OF CERTIFICATES	REQUESTED	
Country Name ARGENTINA	Number o	of Certificates Additional Certificates
Total Fee: \$175		
EXPORTER'S CERTIFICATIO	ON STATEMENT	EDIT
facility named immediat (FDA) that the facility(s) are to the best of my kn and Cosmetic Act (the A following:	ely above, I hereby cert ) and the products ident owledge in substantial c .ct) and all applicable or	to represent and act on behalf of the ify to the Food and Drug Administration fifed on the Supplementary Information compliance with the Federal Food, Drug, pertinent regulations including the
has listed each of the Act and 21 CFi 2. Each product(s) id and is the subject 3. Each product(s) id current enforceme 4. All manufacturers, manufacturing pro 5. The requesting fad operating in subst	Its products identified for R Part 207 or 607; lentified for export is leg of a Marketing Authoriz lentified is not subject o int action initiated by FD contract manufacturers coss have been identifie lithy and all facilities inv antial compliance with C product(s); and	, and contract sterilizers involved in the
for the identified p 6. Each product(s) id		
<ol> <li>Each product(s) id</li> <li>I hereby make this certi that the making or subn States Code Title 18, Ch fines and up to five year</li> </ol>	fication of compliance st hission of false statemer lapter 47, Section 1001. 's imprisonment.	atement for FDA with full knowledge ts represent violations of the United Penalties include up to \$250,000 in
<ol> <li>Each product(s) id</li> <li>I hereby make this certi that the making or subtraction that the making or subtraction States Code Title 18, Ch fines and up to five year</li> <li>"I Agree</li> </ol>	fication of compliance st nission of false statemer Iapter 47, Section 1001. rs imprisonment. Da	its represent violations of the United Penalties include up to \$250,000 in ite: 02/27/2023
<ol> <li>Each product(s) id</li> <li>I hereby make this certi that the making or subn States Code Title 18, Ch fines and up to five year</li> </ol>	fication of compliance st nission of false statemer Iapter 47, Section 1001. rs imprisonment. Da	ts represent violations of the United Penalties include up to \$250,000 in

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**

	Get Help 🕜
Choose how to modify the application	
O Modify a field or fields based on a notification received	
O Request additional certificates	
O Cancel an application	
Cancel < Continue	

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

Select	Application Number	n Date of Application	Certificate Type	Status
0	0340-13 Back	08/02/2013 Continue	Certificate to Foreign Government (CFG) - Standard	Ready for Review

## **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 🄇
created Date: 02/27/2023		Certificate Type: Certificate of a F	Pharmaceutical Product (CPP)
pplication Number: 0016-23		Application Status: Ready for Re	
REQUESTOR INFORMATIO	н .		
lame:Ms. Samantha Lee		Address: 1818 Libra Reston, VA 20190	ary St
irm: ATEK		UNITED STATES	
elephone number: 703- 234567	FAX Number:	Email address: phay	vady.lee@fda.hhs.gov
irm Tax ID code: 11 - 111111		Alternate Email Add	iress:
- Billing Address			
	me as the requester	address? Yes No	
Account Number:			
Delivery Method: Regular Mai	Label File details:		
SECTION 1.1			
Proprietary name: Test Prop Dosage form: Test Dosage for			
Foreign Brand Name: Test fo	reign brand name		
SECTION 1.2, 1.3 & 1.4			
Active ingredient: Test Active Amount per unit dose: Test			
-*Restrictions on Sale?			
Are there restrictions of sale	a, distribution or adm	inistration of the product specified	in the marketing authorization?  Yes
Product Marketed in Export	ling Country		
		ifying country or within the jurisdict	ion of the certifying regional authority?
Ves No			
lest	16775146	24634 searchApplication-flow (4),	pdf
SECTION 2A.1 & 2A.2			
	Address the same as	the Requestor Name and Address	s? © Yes O No
Aarketing Authorization: STN1	11111 - 1111	Date of issue: 01/12/20	22 Biologics License
SECTION 2A.3		bale of 153de, of 17220	22 Number (BLN): 1111
- Status of Marketing Auth	orization Holder (m	ark appropriate items(s)):	
Manufacturer 🗌 Pa			
- Marketing Authorization Ho	Ider Address		
Is the Applicant Name and	Address the same as	s the Requestor Name and Address	s? 🖲 Yes 🔿 No
SECTION 3.1			
Firm: ATEK		Address (P.O. Box 1818 Library St	not acceptable):
License number (if applicab	le):	1818 Library St Reston, VA 20190 UNITED STATES	
Role of Manufacturer: Finish	ed Pharmaceutical F		
Date of Last FDA inspection	:	Registration numb Address (P.O. Box	
Firm: ATEK 2		123 Main St Reston, VA 20190	not acceptable).
License number (if applicab		UNITED STATES	
Role of Manufacturer: Bulk F Date of Last FDA inspection		Registration numb	er: 1004782
Firm: ATEK 3		Address (P.O. Box	
License number (if applicab	le):	1818 Library St Reston, VA 20190 UNITED STATES	
Role of Manufacturer: Solve	nt and Diluents	011120 011120	
Note of manufacturer: Solve	:	Registration numb	er: 1004369
Role of Manufacturer: Solve Date of Last FDA inspection			
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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	Figure 9:	Update	Number	of Certificates	Requested
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NUMBER OF CERTIFICATES REQUESTED				
Enter the number of	certificates requested.			
Country Name	Original Certificate	Additional Copies	Request Additional Copies	
ALBANIA	1			
Cancel	ontinue			

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

	Get Help 🕜
Choose how to modify the application	
O Modify a field or fields based on a notification received	
O Request additional certificates	
O Cancel an application	
Cancel < Continue	

**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 <u>CBERBECATS@fda.hhs.gov</u> 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

Select	Application Number	Date of Application	Certificate Type	Status
0	0340-13	08/02/2013	Certificate to Foreign Government (CFG) - Standard	Ready for Review
	Back C	ontinue		

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**

Warning: Application will be cancelled. Do you wish to continue?		
K Back	Continue	]

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

