


NRC FORM 7 (02-2016) 10 CFR 110		U. S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0027 EXPIRES: 11/30/2018 Estimated burden per response to comply with this mandatory collection request 2.4 hours. This submittal is reviewed to ensure that the applicable statutory, regulatory, and policy considerations are satisfied. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0027), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.						
APPLICATION FOR NRC EXPORT OR IMPORT LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) <i>(See Instructions on Pages 4 and 5)</i>									
PART A. FOR NRC USE ONLY		<input checked="" type="checkbox"/> PUBLIC OR <input type="checkbox"/> NON-PUBLIC							
LICENSE NUMBER <u>XMA7443</u>		DOCKET NUMBER <u>11006301</u>							
ADAMS ACCESSION NUMBER <u>ML180731063</u>		DATE RECEIVED <u>8/13/18</u>							
PART B. TO BE COMPLETED FOR ALL LICENSES, AMENDMENTS, RENEWALS, OR CONSENT REQUESTS (If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)									
1. NAME AND ADDRESS OF APPLICANT/LICENSEE Vertex Pharmaceuticals Incorporated 50 Northern Ave Boston, MA 02210		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> 1a. NAME OF APPLICANT'S CONTACT Paula Rothwell </td> <td style="width: 50%; vertical-align: top;"> 1b. APPLICANT'S REFERENCE NUMBER </td> </tr> <tr> <td style="vertical-align: top;"> 1c. PHONE NUMBER (617) 835-9857 </td> <td style="vertical-align: top;"> 1d. FAX NUMBER (857) 263-4405 </td> </tr> <tr> <td colspan="2" style="vertical-align: top;"> 1e. E-MAIL ADDRESS Paula_Rothwell@vrtx.com </td> </tr> </table>		1a. NAME OF APPLICANT'S CONTACT Paula Rothwell	1b. APPLICANT'S REFERENCE NUMBER	1c. PHONE NUMBER (617) 835-9857	1d. FAX NUMBER (857) 263-4405	1e. E-MAIL ADDRESS Paula_Rothwell@vrtx.com	
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2. TYPE OF ACTION REQUESTED (Check One) <table style="width: 100%;"> <tr> <td style="width: 25%;"><input checked="" type="checkbox"/> EXPORT (Parts B, C, E)</td> <td style="width: 25%;"><input type="checkbox"/> IMPORT (Parts B, D, E)</td> <td style="width: 25%;"><input type="checkbox"/> AMENDMENT/RENEWAL Current License Number: _____</td> <td style="width: 25%;"><input type="checkbox"/> CONSENT REQUEST (Parts B, C) Current License Number: _____</td> </tr> </table>				<input checked="" type="checkbox"/> EXPORT (Parts B, C, E)	<input type="checkbox"/> IMPORT (Parts B, D, E)	<input type="checkbox"/> AMENDMENT/RENEWAL Current License Number: _____	<input type="checkbox"/> CONSENT REQUEST (Parts B, C) Current License Number: _____		
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3. CONTRACT NUMBER(S)	4. FIRST SHIPMENT DATE 2/1/2018	5. LAST SHIPMENT DATE 2/1/2023	6. PROPOSED EXPIRATION DATE						
PART C. TO BE COMPLETED FOR EXPORT LICENSES, AMENDMENTS, OR RENEWALS (If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)									
7. NAME(S) / ADDRESS(ES) OF SUPPLIERS AND/OR OTHER PARTIES TO THE EXPORT Exporter : Vertex Pharmaceuticals 50 Northern Ave Boston, MA 02210 Also see page 3 for additional Supplier addresses		8. NAME(S) / ADDRESS(ES) OF INTERMEDIATE FOREIGN CONSIGNEE(S) Also see page 3 for additional addresses							
9. NAME(S) / ADDRESS(ES) OF ULTIMATE FOREIGN CONSIGNEE(S) Shanghai SynTheAll Pharmaceutical Co., Ltd. 9 Yuegong Road, Jinshan District, Shanghai 201507 China Also see page 3 for additional addresses		10. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES, EQUIPMENT, OR COMPONENTS; FOR NUCLEAR EQUIPMENT INCLUDE TOTAL DOLLAR VALUE OF EQUIPMENT FOR EXPORT Non-radioactive Deuterium gas Deuterium oxide Deuterium compounds							
7a. FUNCTION(S) PERFORMED/SERVICE(S) PROVIDED Supplier/Distributor		8a. INTERMEDIATE USE(S)							
9a. ULTIMATE END USE(S) See page 3		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; vertical-align: top;"> 10a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq) 5000 kgs </td> <td style="width: 33%; vertical-align: top;"> 10b. MAX ENRICHMENT OR WGT % 99.99% </td> <td style="width: 33%; vertical-align: top;"> 10c. MAX ISOTOPE WGT (KG) N/A non-radioactive material, not radioactive waste </td> </tr> </table>		10a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq) 5000 kgs	10b. MAX ENRICHMENT OR WGT % 99.99%	10c. MAX ISOTOPE WGT (KG) N/A non-radioactive material, not radioactive waste			
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11. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME)									

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U. S. NUCLEAR REGULATORY COMMISSION

**APPLICATION FOR NRC EXPORT OR IMPORT
LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)**

LICENSE NUMBER XMAT443	DOCKET NUMBER 1100630	ADAMS ACCESSION NUMBER	<input checked="" type="checkbox"/> PUBLIC OR <input type="checkbox"/> NON-PUBLIC
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PART D. TO BE COMPLETED FOR IMPORT LICENSES, AMENDMENTS, OR RENEWALS

(If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)

12. NAME(S) / ADDRESS(ES) OF FOREIGN SUPPLIERS AND/OR OTHER PARTIES TO IMPORT	13. NAME(S) / ADDRESS(ES) OF INTERMEDIATE CONSIGNEE(S)	14. NAME(S) / ADDRESS(ES) OF ULTIMATE U. S. CONSIGNEE(S)	
12a. NRC EXPORT LICENSE NUMBER(S) (if applicable)	13a. LICENSE NUMBER(S) / EXPIRATION DATE(S)	14a. LICENSE NUMBER(S) / EXPIRATION DATE(S)	
	13b. INTERMEDIATE USE(S)	14b. ULTIMATE END USE(S)	
15. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES	15a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)	15b. MAX ENRICHMENT OR WGT %	15c. MAX ISOTOPE WGT (KG)

16. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME)

PART E. TO BE COMPLETED FOR ALL LICENSES, AMENDMENTS, RENEWALS OR CONSENT REQUEST(S)

17. ADDITIONAL INFORMATION PROVIDED ON PAGES 3, 4, AND/OR ON SEPARATE SHEETS?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	17a. COPIES OF RECIPIENTS' AUTHORIZATIONS PROVIDED?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
18. CERTIFICATION: I, the applicant's authorized official, hereby certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, and that all information provided is correct to the best of my knowledge.			
18a. PRINT NAME AND TITLE OF AUTHORIZED OFFICIAL Paula Rothwell Logistics Manager		18b. SIGNATURE -- AUTHORIZED OFFICIAL 	18c. DATE 1-30-18

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U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR NRC EXPORT OR IMPORT LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)

LICENSE NUMBER

XMA1443

DOCKET NUMBER

11006301

ADAMS ACCESSION NUMBER



PUBLIC

OR



NON-PUBLIC

ADDITIONAL INFORMATION (Reference applicable block numbers from page 1 and/or page 2 for each entry)

NRC7. Part C. 7 (Cont.) NAME(S) / ADDRESS(ES) OF SUPPLIERS AND/OR OTHER PARTIES TO THE EXPORT

Cambridge Isotope Laboratories, Inc.
50 Frontage Road
Andover MA 01810

Aldrich Chemical Co. LLC
6000 N. Teutonia Avenue
Milwaukee, WI 53209

Aldrich Chemical Co. LLC
3858 Benner Road
Miamisburg, OH 45342

Sigma Aldrich Fine Chemicals (SAFC)
5485 County Road V
Sheboygan Falls, WI 53085, USA

NRC7. Part C. 9a - Ultimate foreign consignee(s) (Cont.)

Changzhou SynTheAll Pharmaceutical Co., Ltd
589 North Yulong Road
XinBei District
Changzhou 213127
China

CARBOGEN AMCIS (Shanghai) Co., Ltd.
No. 69 Shungong Road
Shanghai Chemical Industry Park
Shanghai
China

NRC7. Part C. 9a Ultimate end use

Vertex plans to utilize the deuterium compounds to manufacture active pharmaceutical ingredients (APIs). These APIs will be utilized in clinical trials as part of a potential triple combination therapy for the treatment of Cystic Fibrosis. No material will be used in any activity related to isotope separation , heavy water production , or in the fabrication of nuclear fuel.