

<b>NRC FORM 7</b> <small>(11-2012)</small> <small>10 CFR 110</small>	 <b>U. S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0027</b>	<b>EXPIRES: (11/30/2015)</b>
<b>APPLICATION FOR NRC EXPORT OR IMPORT LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S)</b> <i>(See Instructions on Pages 4 and 5)</i>		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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to <a href="mailto:infocollects.Resource@nrc.gov">infocollects.Resource@nrc.gov</a> , and to the Desk Officer, Office of Information and Regulatory Affairs, NECB-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.	

<b>PART A. FOR NRC USE ONLY</b>	<input checked="" type="checkbox"/> PUBLIC OR <input type="checkbox"/> NON-PUBLIC	<b>DATE RECEIVED</b> DEC 05 2013 JC
LICENSE NUMBER <b>XMAT 431</b>	DOCKET NUMBER <b>11006131</b>	ADAMS ACCESSION NUMBER

**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.)

<b>1. NAME AND ADDRESS OF APPLICANT/LICENSEE</b>  Concert Pharmaceuticals, Inc. 99 Lexington Avenue, Suite 500 Lexington, MA 02421	<b>1a. NAME OF APPLICANT'S CONTACT</b> Jeffrey I. Kessler	<b>1b. APPLICANT'S REFERENCE NUMBER</b> N/A
	<b>1c. PHONE NUMBER</b> (202) 663-6212	<b>1d. FAX NUMBER</b> (202) 663-6363
	<b>1e. E-MAIL ADDRESS</b> jeffrey.kessler@wilmerhale.com	

**2. TYPE OF ACTION REQUESTED (Check One)**

EXPORT (Parts B, C, E)     
  IMPORT (Parts B, D, E)     
  AMENDMENT/RENEWAL Current License Number: \_\_\_\_\_     
  CONSENT REQUEST (Parts B, C) Current License Number: \_\_\_\_\_

3. CONTRACT NUMBER(S)	4. FIRST SHIPMENT DATE 1/1/2014	5. LAST SHIPMENT DATE 12/31/2019	6. PROPOSED EXPIRATION DATE 12/31/2019
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**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.)

<b>7. NAME(S) / ADDRESS(ES) OF SUPPLIERS AND/OR OTHER PARTIES TO THE EXPORT</b> Cambridge Isotope Laboratories, Inc. 50 Frontage Road Andover, MA 01810-5413	<b>8. NAME(S) / ADDRESS(ES) OF INTERMEDIATE FOREIGN CONSIGNEE(S)</b>	<b>9. NAME(S) / ADDRESS(ES) OF ULTIMATE FOREIGN CONSIGNEE(S)</b> Hovione FarmaCiencia SA Sete Casas 2674-506 Loures Portugal  DSM Fine Chemicals Austria Nfg GmbH & Co KG St.-Peter-Strasse 25 A-4021 Linz Austria
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7a. FUNCTION(S) PERFORMED/SERVICE(S) PROVIDED Supply D2O for export	8a. INTERMEDIATE USE(S)	9a. ULTIMATE END USE(S) Use D2O in API manufacture
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<b>10. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES, EQUIPMENT, OR COMPONENTS; FOR NUCLEAR EQUIPMENT INCLUDE TOTAL DOLLAR VALUE OF EQUIPMENT FOR EXPORT</b>  Heavy water (D2O)	<b>10a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)</b>  ~20,000 kgs (liters) over license life	<b>10b. MAX ENRICHMENT OR WGT %</b>  >99% enrichment relative to water (H2O)	<b>10c. MAX ISOTOPE WGT (KG)</b>  N/A (D2O is not radioactive waste)
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**11. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME)**  
 Not yet determined



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LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)

LICENSE NUMBER <b>XMAT 431</b>	DOCKET NUMBER <b>11006131</b>	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.)

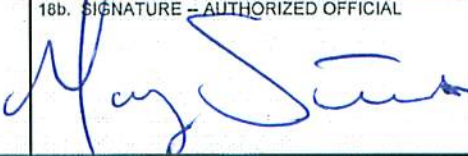
12. NAME(S) / ADDRESS(ES) OF FOREIGN SUPPLIERS AND/OR OTHER PARTIES TO IMPORT	13. NAME(S) / ADDRESS(ES) OF INTERMEDIATE CONSIGNEE(S)	14. NAME(S) / ADDRESS(ES) OF ULTIMATE U. S. CONSIGNEE(S)	
12a. NRC EXPORT LICENSE NUMBER(S) (if applicable)	13a. LICENSE NUMBER(S) / EXPIRATION DATE(S)	14a. LICENSE NUMBER(S) / 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
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**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 Nancy Stuart, Chief Operating Officer	18b. SIGNATURE - AUTHORIZED OFFICIAL 	18c. DATE 8/29/13
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ADDITIONAL INFORMATION (Reference applicable block numbers from page 1 and/or page 2 for each entry)

This license application relates to exports of heavy water for a non-nuclear end-use. In particular, the foreign ultimate consignees ("UCs", listed in block 9) will process heavy water exported under this license to achieve a hydrogen-deuterium exchange, as part of the manufacture of active pharmaceutical ingredients (APIs) (as indicated in Block 9a). As indicated in Block 11, Concert Pharmaceuticals, Inc. ("Concert", listed in Block 1) has not yet determined the quantities of heavy water (if any) to be exported under this license to each of the foreign UCs. However, in the aggregate, the quantity of heavy water exported under this license will not exceed 20,000 kg (as indicated in Block 10a) - unless Concert applies for, and NRC issues, an amendment to the license approving an increase in quantity.

Please note that Concert and/or Cambridge Isotope Laboratories, Inc. (listed in Block 7) may apply for further export licenses in the future in connection with Concert's interest in exporting heavy water to manufacture APIs. In addition, Concert plans to import to the United States any heavy water that remains unutilized at the completion of the manufacturing process undertaken by the foreign UCs, for re-enrichment in the United States and possibly for subsequent export under this license.

Concert is only submitting pages 1 and 3 of the license application at the present time. The original signed hardcopy version of page 2 was previously submitted on November 7, 2013, as part of an application to amend Concert's existing export license XMAT414. On November 20, 2013, NRC contacted Mr. Kessler (listed in Block 1) proposing to issue a new license rather than amending XMAT414. On November 26, 2013, the NRC requested that Mr. Kessler submit a new version of pages 1 and 3 of the license application. Pursuant to this request, Mr. Kessler is now submitting this page and page 1.

DEC 05 2013  
JC