NRC FORM 7 (11-2012) 10 CFR 110

U. S. NUCLEAR REGULATORY COMMISSION

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

(See Instructions on Pages 4 and 5)

APPROVED BY OMB: NO. 3150-0027 EXPIRES: (11/30/2015)

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 Infocollects.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.

PART A. FOR NRC USE ONLY	☑ PUBLIC OR ☐ NON-PUBLIC	DATE RECEIVED
		12-3-13
LICENSE NUMBER	DOCKET NUMBER	ADAMS ACCESSION NUMBER
XB1330	11006130	

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	1a. NAME OF APPLICANT'S CONTACT	1b. APPLICANT'S REFERENCE NUMBER
MP Biomedicals LLC 3 Hutton Centre Drive #100 Santa Ana, CA 92707	Bill Richardson	
	1c. PHONE NUMBER: (440) 337-1200	1d. FAX NUMBER: (440) 337-1180
	1e. E-MAIL ADDRESS: warichardson@mpbio.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	5. LAST SHIPMENT DATE	6. PROPOSED EXPIRATION DATE
	within 1-3 weeks of approval	ongoing	12/31/2018

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	8. NAME(S) / ADDRESS(ES) OF INTERMEDIATE FOREIGN CONSIGNEE(S)	9. NAME(S) / ADDRESS(ES) OF ULTIMATE FOREIGN CONSIGNEE(S)
MP Biomedicals, LLC 29525 Fountain Parkway Solon, Ohio 44139 USA	Mohammad T. Lotfi-Jam (Managing Director) Yavaran Teb Jam Company 41 Khaghani Street, Darvazehdolat Tehran 1571913371, Iran	1) Bernard Laboratory, Haft Tir Sq., Mazandarani Alley., No. 18 Tehran, Iran 2) Boghrat Laboratory, Piroozi St., No.100 Tehran, Iran 3) Chehr Laboratory, Shariati St., No. 1006 Tehran, Iran 4) Danesh Laboratory, Vesal Shirazi St., Fard Danesh St., No. 23 Tehran, Iran 5) Day Hospital, Vali Asr St., Shahid Abbas Pour St., Tehran Iran
7a. FUNCTION(S) PERFORMED/SERVICE(S) PROVIDED	8a. INTERMEDIATE USE(S)	9a. ULTIMATE END USE(S)
Medical Diagnostic Kits		Medical Diagnostic Kits

10. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES, EQUIPMENT, OR COMPONENTS; FOR NUCLEAR EQUIPMENT INCLUDE TOTAL DOLLAR VALUE OF EQUIPMENT FOR EXPORT	10a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)	10b. MAX ENRICHMENT OR WGT %	10c. MAX ISOTOPE WGT (KG)
Laboratory diagnostic kits which each contain <20 µCi of byproduct material. All but one of the kits contain only iodine-125, and one kit contains both iodine-125 and cobalt-57. These isotopes are provided in an aqueous solution, and they are bound to steroid or polypeptide hormones or to antibodies to those hormones. The maximum total activity for all kits over the requested five year license...	For the maximum five year license life: 0.03 TBq	N/A	N/A

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

ACK JW 12-3-13

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

LICENSE NUMBER	DOCKET NUMBER	ADAMS ACCESSION NUMBER	
XB1330	11006130		☑ PUBLIC OR ☐ NON-PUBLIC

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?	☑ YES ☐ NO	17a. COPIES OF RECIPIENTS' AUTHORIZATIONS PROVIDED?	☐ YES ☐ NO

18. CERTIFICATION: I, the applicant's authorized official, hereby certify that this application is prepared in conformity with Title10, 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	18b. SIGNATURE – AUTHORIZED OFFICIAL	18c. DATE
BILL RICHARDSON DIRECTOR OF TECHNICAL OPERATIONS	Bill Rid	11-14-13

Rec'd Jan 15 '13

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

LICENSE NUMBER	DOCKET NUMBER	ADAMS ACCESSION NUMBER	☑ PUBLIC OR ☐ NON-PUBLIC
XB1330	11 CFR 6130		

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

C7a. Description of the Products:
There are twenty laboratory diagnostic kits that are the subject of these four classification requests and each are described below. None of these kits are point of care.

Description of Isotopes (Iodine-125 and Cobalt-57) Contained in the Diagnostic Kits:
Each kit contains iodine-125. One kit, the B12/Folate-SNB Kit 100T, also contains cobalt-57 in addition to iodine-125.

The iodine is used to generate the signal which allows the laboratory technician to quantify the level of hormone present in a patient sample. When iodine-125 decays, it produces a gamma ray which can be detected using a laboratory gamma counter. At the conclusion of the test, the amount of iodine-125 remaining in the assay tube is proportional (sometimes inversely proportional) to the amount of hormone being measured. MP Biomedicals is not aware of any other uses for the iodine-125 (or cobalt-57) used in the kits. It is important to note that these isotopes are linked (bound) to the hormone being tested. They are not free isotopes in solution. For example, the iodine-125 contained in the Testosterone kit is linked to a testosterone derivative. It is provided in the kit as testosterone-histamine-125I. Any other application would require the significant effort to uncouple the iodine-125 from the hormone and isolate it.

Description of the Individual Kits:
(1) T3 Uptake Kit 100T: 125 RIA Kit for the in-vitro determination of percentage of T3 uptake in 0.025 mL of human serum or plasma; and
(2) Androstenedione Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of androstenedoine in 0.3 mL of extracted human serum or plasma; and
(3) DHEA Sulfate Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of DHEA-sulfate in 0.025 mL of human serum or plasma.
(4) Testosterone Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of testosterone in 0.05 mL of human serum or plasma.
(5) Progesterone Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of progesterone in 0.1 mL of human serum or plasma.
(6) Free T4 Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of unbound (free) T4 in 0.05 mL of human serum or plasma.
(7) LH Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human luteinizing hormone in 0.1 mL of human serum or plasma.
(8) Growth Hormone Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human growth hormone in 0.1 mL of human serum or plasma.
(9) Total T4 Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of T4 in 0.025 mL of human serum or plasma
(10) 17OH-Progesterone Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of 17OH-progesterone in 0.01 mL of human serum or plasma.
(11) Free T3 Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of unbound (free) T3 in 0.1 mL of human serum or plasma.
(12) Total T3 Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of T3 in 0.1 mL of human serum or plasma.
(13) Cortisol Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of cortisol in 0.025 mL of human serum or plasma.
(14) ACTH Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human ACTH in 0.1 mL of human EDTA plasma.
(15) Prolactin Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human prolactin in 0.025 mL of human serum
(16) FSH Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human follicle stimulating hormone in 0.1 mL of human serum or plasma

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C7a. Continued:
(17) Insulin Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human insulin in 0.1 mL of human serum or EDTA plasma.

(18) Ferritin Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of ferritin in 0.04 mL of human serum.

(19) TSH Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of human thyroid stimulating hormone in 0.2 mL of human serum or plasma.

(20) B12/Folate-SNB Kit 100T: FDA cleared 125I RIA Kit (100 tubes) for the in-vitro determination of vitamin B12 and folate in 0.2 mL of human serum, plasma, or whole blood hemolysate. This kit also contains cobalt-57. The B12/Folate-SNB Kit contains the chemical potassium cyanide (ECCN 1C350.d.12). For each of the two kit components, the concentrations are low: tracer - 0.03%; standards - 0.003%. The total amount of potassium cyanide per kit is only 0.004 grams. Potassium cyanide is required for the proper measurement of vitamin B12 in human serum or plasma. It is used in the assay to convert the "non-cyano" forms of vitamin B12 (hydroxocobalamin, adenosylcobalamin and methylcobalamin) to cyanocobalamin.

C9.
6) Lamark Laboratory, Seyed Jamaleddin Asad Abadi St., 18 st., No.9 Tehran, Iran
7) Marjan Laboratory, Felestin St., Building 162 Tehran, Iran
8) Masoud Laboratory, Mirdamad St., No. 347 Tehran, Iran
9) Pajohesh Laboratory, Ekbatan St., Secound Faz., No. 26 Tehran, Iran
10) Pars Hospital, Keshavarz Bolv. Tehran, Iran
11) Resalat Hospital, Seyed Khandan Bridje., Abozar Ghafary Alley Tehran, Iran

C10. Continued:
..life is 0.03 TBq. The projected sales would be about per year.

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