DRUG ENFORCEMENT ADMINISTRATION

Supply Chain Conference
Houston, Texas

May 2, 2023

Imports & Exports

The Laws and Regulations relating to
U.S. Imports and Exports

- Title 21 § 951 - Definitions
- Title 21 § 952 - Importation of controlled substances
- Title 21 § 953 - Exportation of controlled substances

- 21 CFR § 1312 - Importation and Exportation of controlled substances

Imports & Exports

	DEA-357	DEA-161	DEA Form-236		DEA Form-486/A	
			Imports	Exports	Imports	Exports
Schedule I & II	✓	✓				
Schedule III Narcotic	✓	✓				
Schedule III Non-Narcotic (7369 requires a PERMIT)			✓	✓		
Schedule IV Narcotic	✓	✓				
Schedule IV Non-Narcotic			✓	✓		
Schedule V Narcotic	✓			✓		
Schedule V Non-Narcotic			✓	✓		
List I & II Chemicals					✓	✓
EPH, PSE, & PPA					✓	

DEA-161

Purpose: The “Application for Permit to Export Controlled Substances” is for any controlled substance in schedule I or II, or any narcotic controlled substance III or IV

To DEA: DEA-161, the foreign import permit or Letter of No Objection (LONO) from the Competent National Authority, and necessary supporting documents for the export

From DEA: DEA 36 (DEA Permit to Export)

DEA-357

Purpose: The “Application for Permit to Import Controlled Substances” is for any controlled substance in schedule I or II, or any narcotic controlled substance III, IV, or V

To DEA: DEA-357, and necessary supporting documents for the import

From DEA: DEA 35 (DEA Permit to Import)

DEA-236 (for Imports & Exports)

Purpose: The “Controlled Substances Import/Export Declaration” is for non-narcotic drugs schedule III, IV, or V (imports) and non-narcotic drugs in schedule III or IV or any controlled substances in schedule V (exports)

To DEA: DEA-236; the foreign Import Permit or Letter of No Objection from the Competent National Authority (for exports); and necessary supporting documents

From DEA: Transaction ID

Online IMEX (Import & Export)

Online IMEX (Import & Export)

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

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REPORTING > Reports Required by 21 CFR > Import/Export Permit Applications and Declarations

Import/Export Permit Applications and Declarations

Only those persons registered with and authorized by DEA to import or export controlled substances may utilize/submit declarations and applications for permits.

Import/Export Online

DEA Form 161 - Application for Permit to Export Controlled Substances
DEA Form 236 - Controlled Substances Import/Export Declaration
DEA Form 357 - Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes
DEA Form 453 - **Notification of Domestic Transactions Involving Listed Chemicals (Coming Soon)**

Import/Export PDF Format

DEA Form 161 - Application for Permit to Export Controlled Substances
DEA Form 161R - Application for Permit to Export Controlled Substances for Subsequent Reexport
DEA Form 236 - Controlled Substances Import/Export Declaration
DEA Form 357 - Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes

Assistance and Support with Medical Missions

References

Quick Reference Guide for Importers/Exporters of Controlled Substances

This is a detailed guide to filling out DEA Forms 357, 161, and 236:

Conversion Factors for Controlled Substances

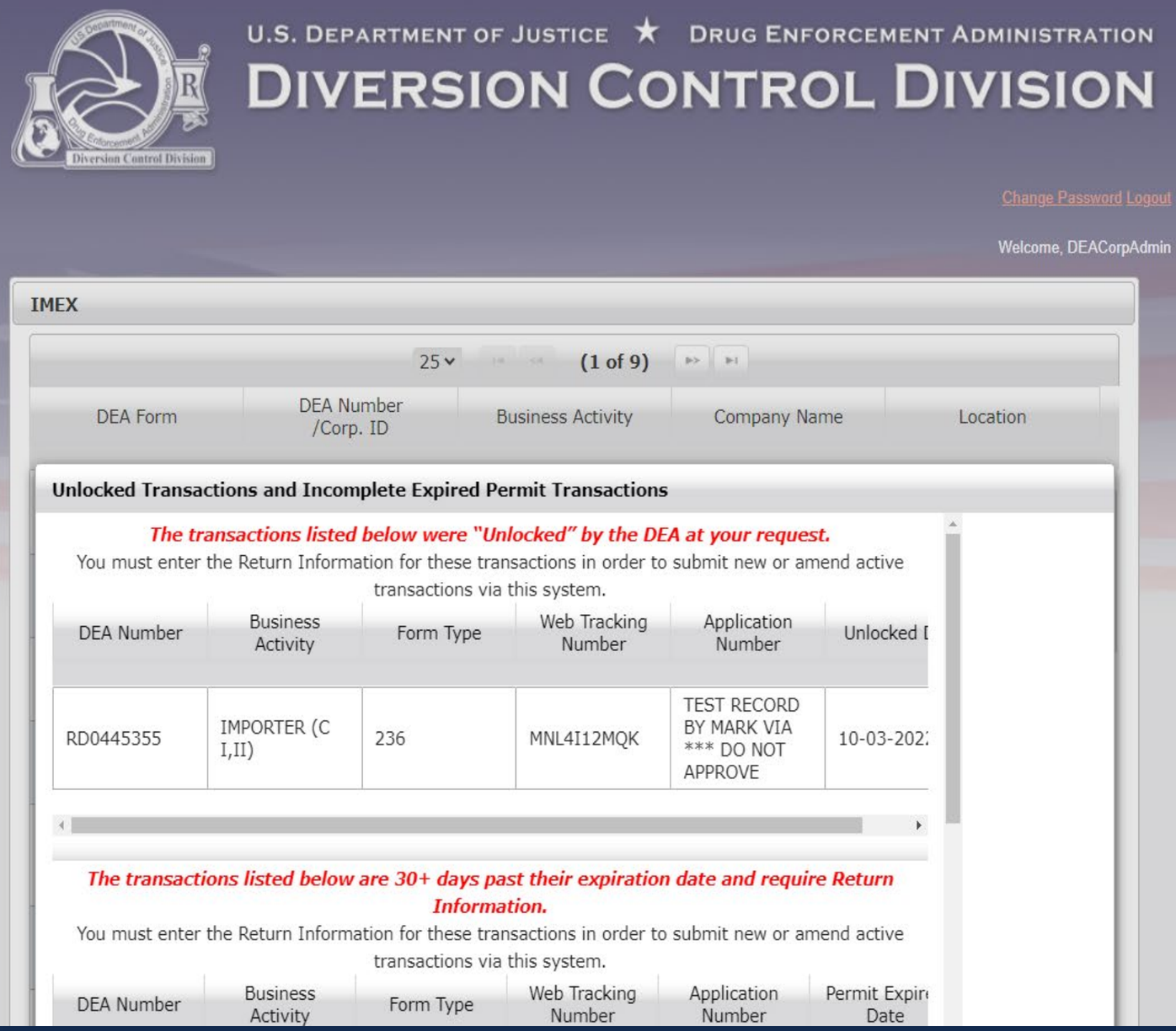
An alphabetical listing of many Schedules I-V controlled substances as listed in Title 21 Codes of Federal Regulations, and their corresponding DEA code numbers and conversion factors.

Get Email Updates:

- ARCOS
- BCM Online
- Chemical Import/Export Declarations
- CSOS (Controlled Substances Ordering System)
- Theft/Loss Reporting
- Import/Export
- Medical Missions
- Quotas
- Registrant Record of Controlled Substances Destroyed
- Regulated Machines (Tableting and Encapsulating)
- Reports Required by 21 CFR
- SORS
- Submit a Tip to DEA
- Year-End Reports

Online IMEX (Import & Export)

Online IMEX (Import & Export)



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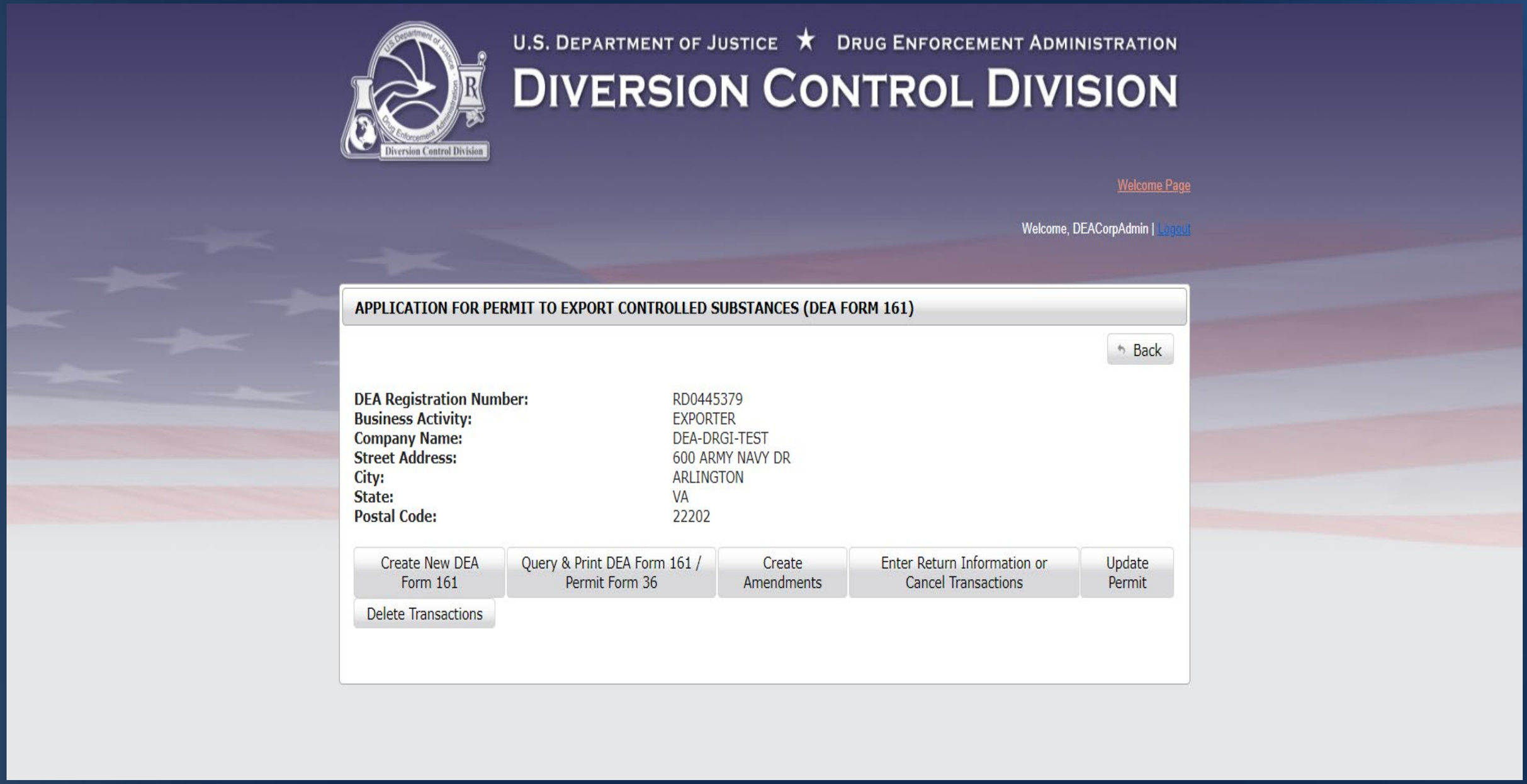

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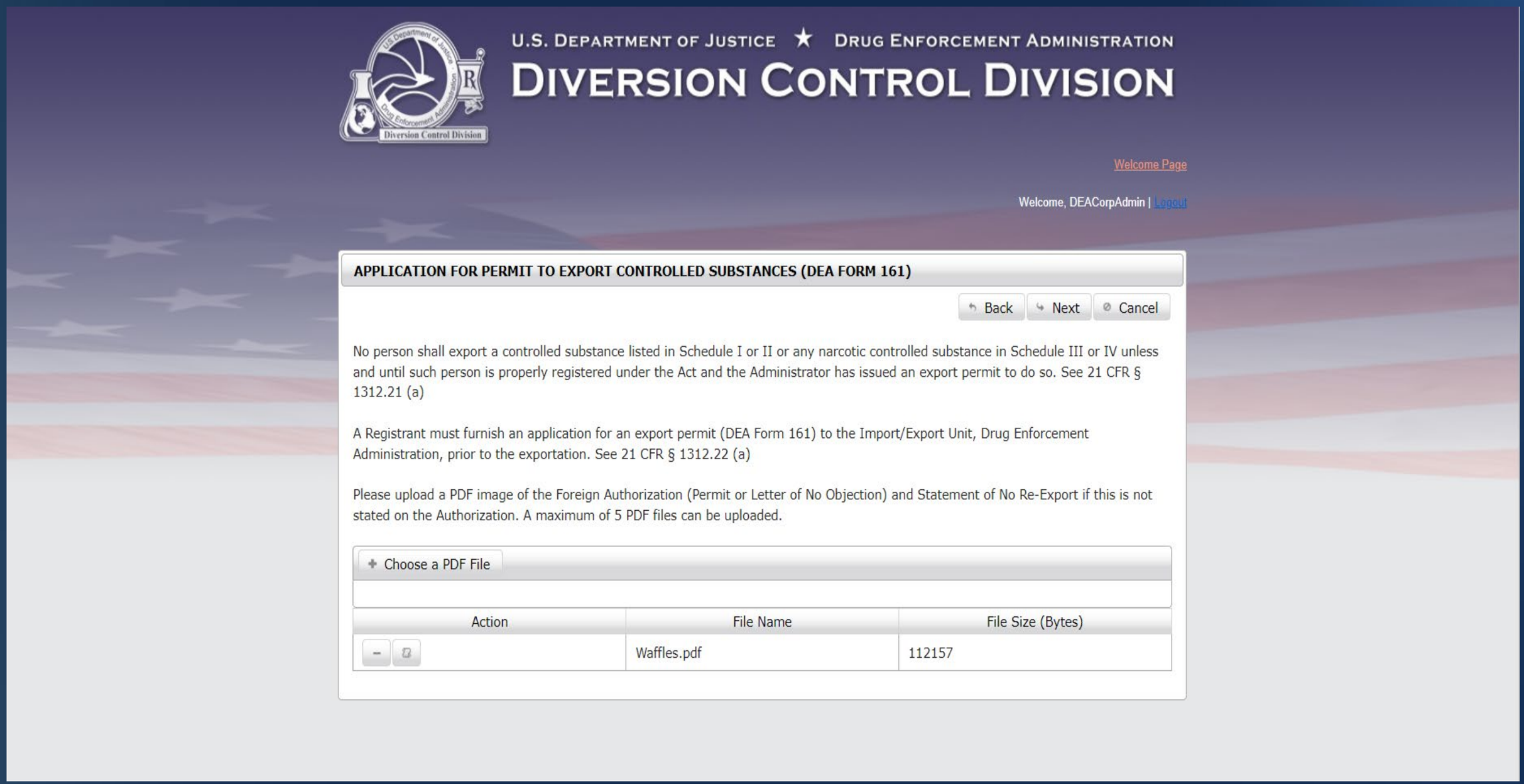

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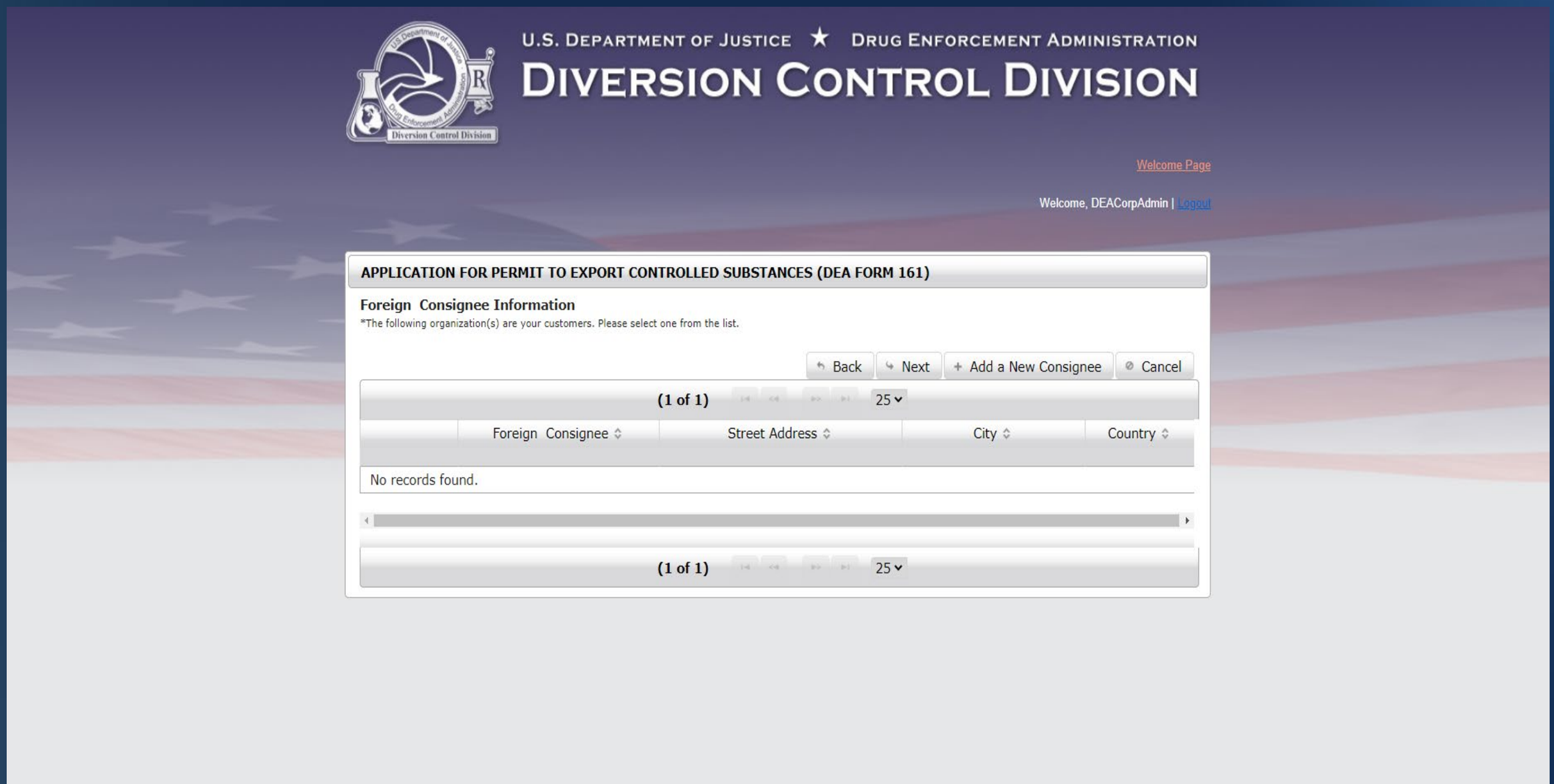

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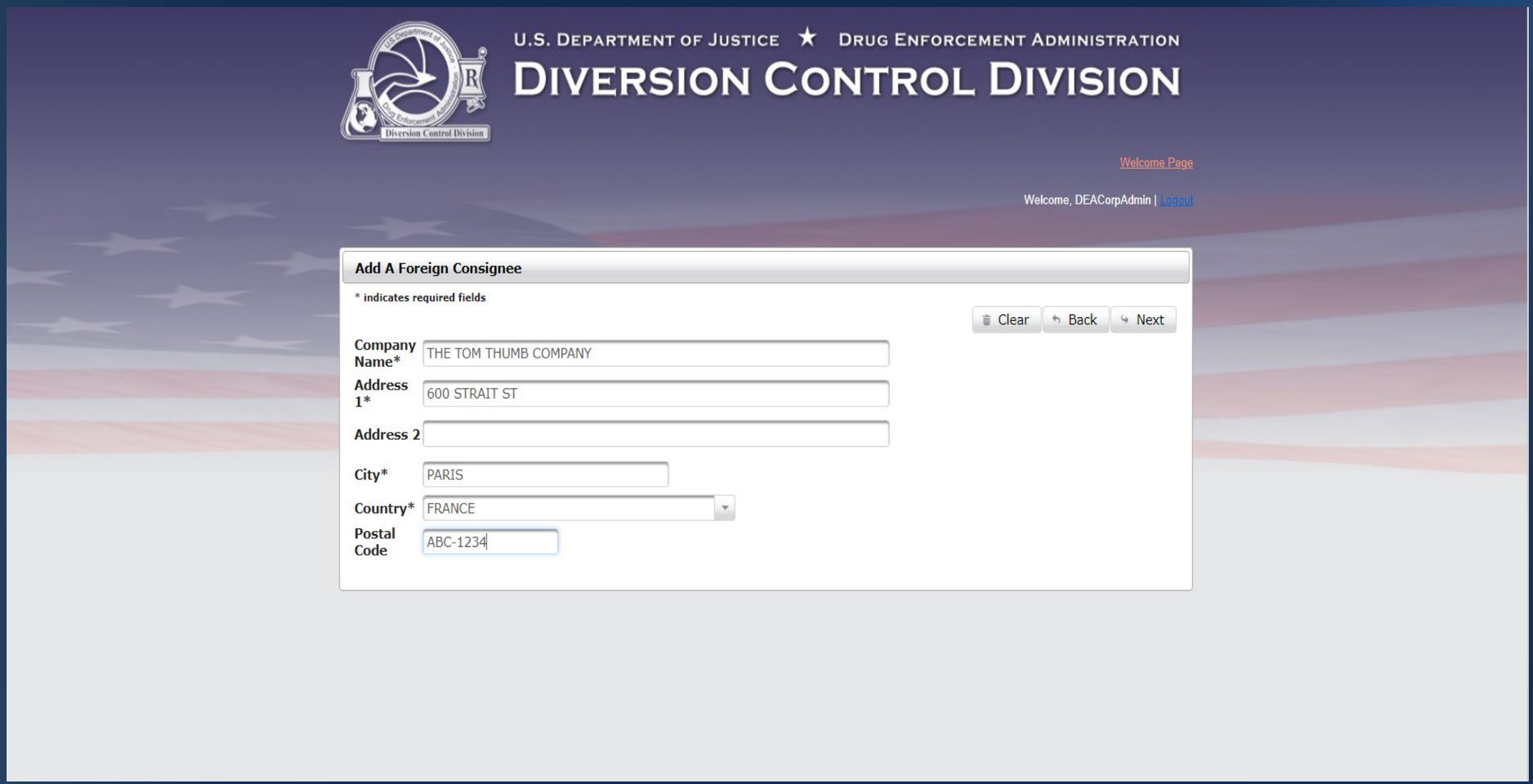

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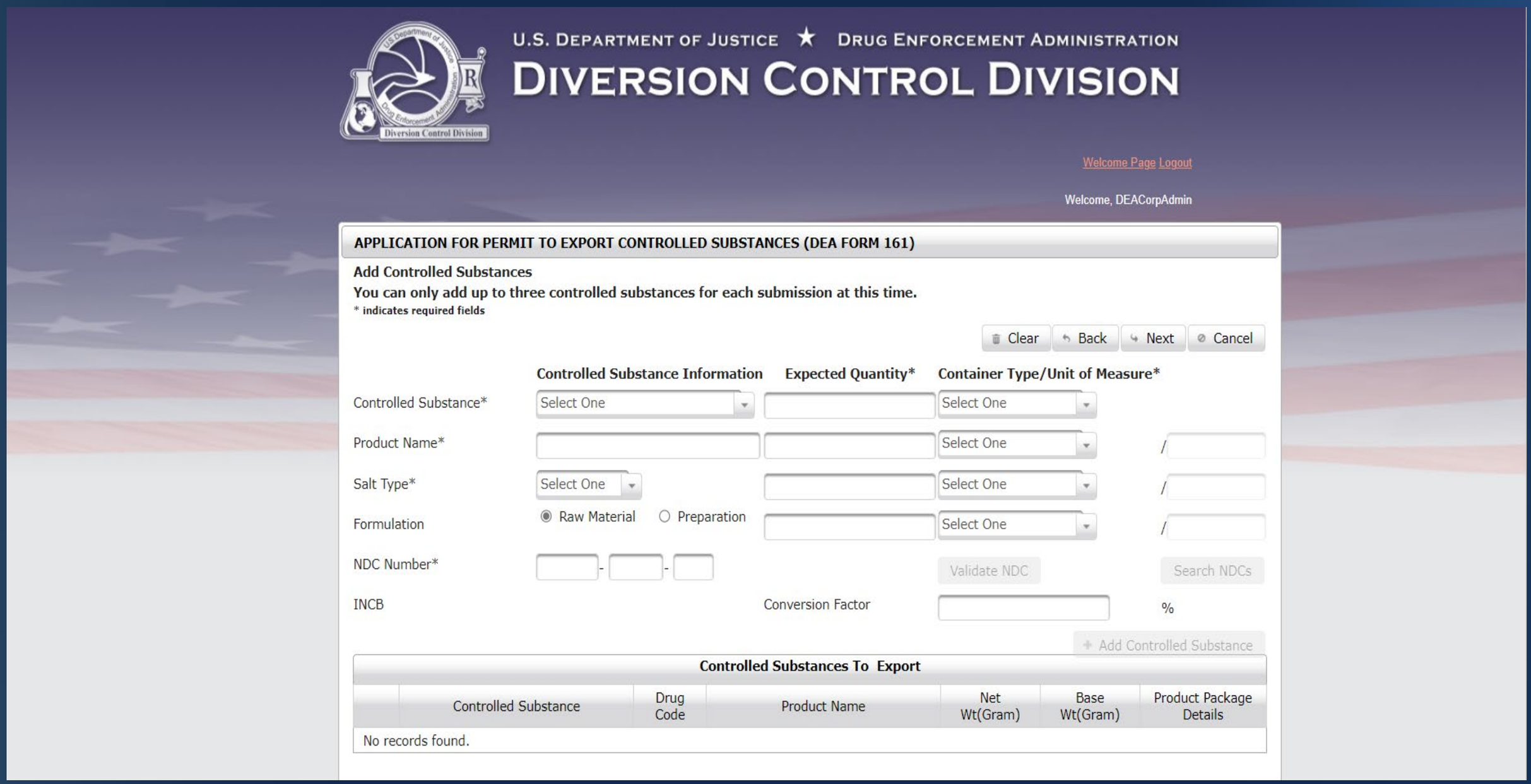

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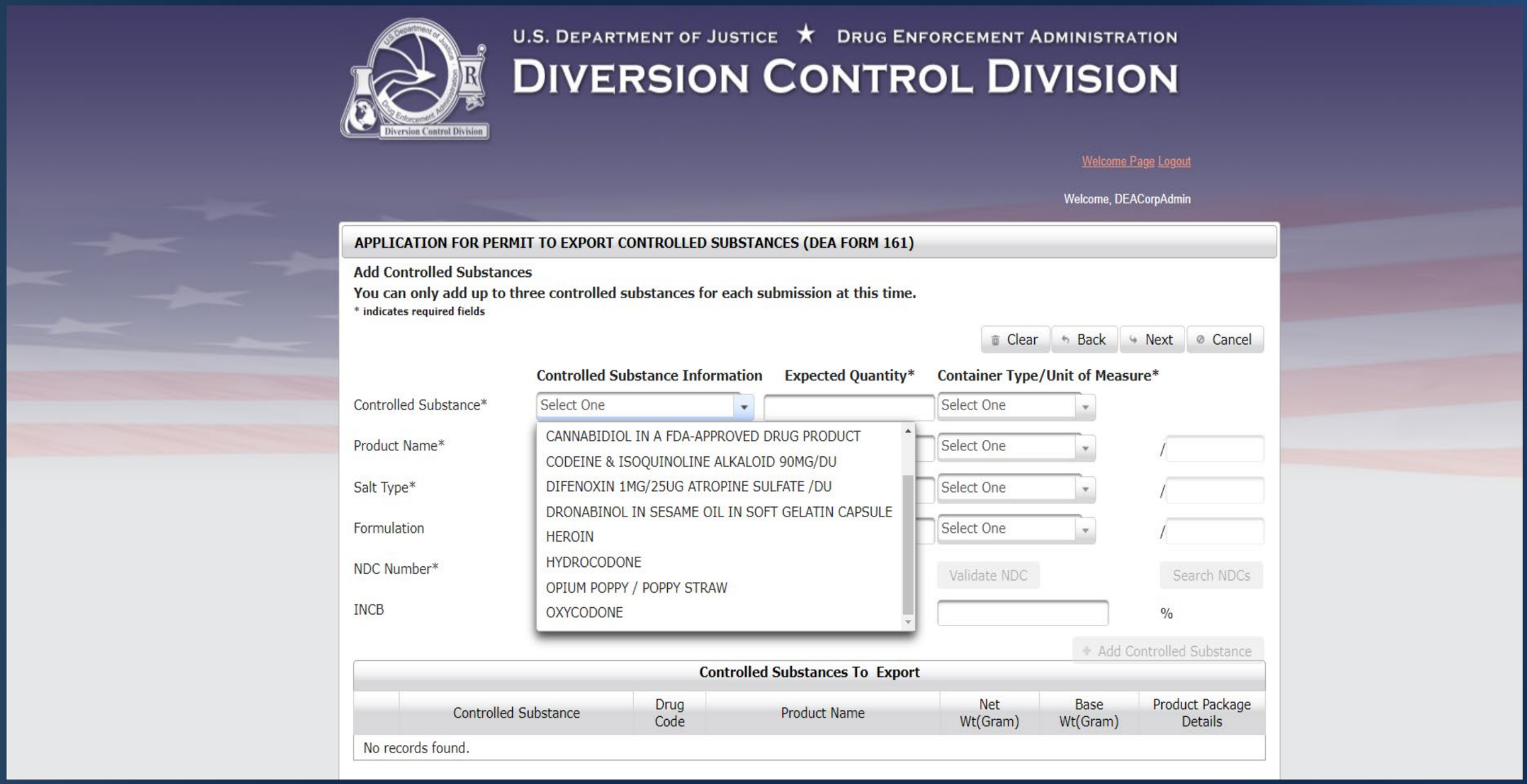

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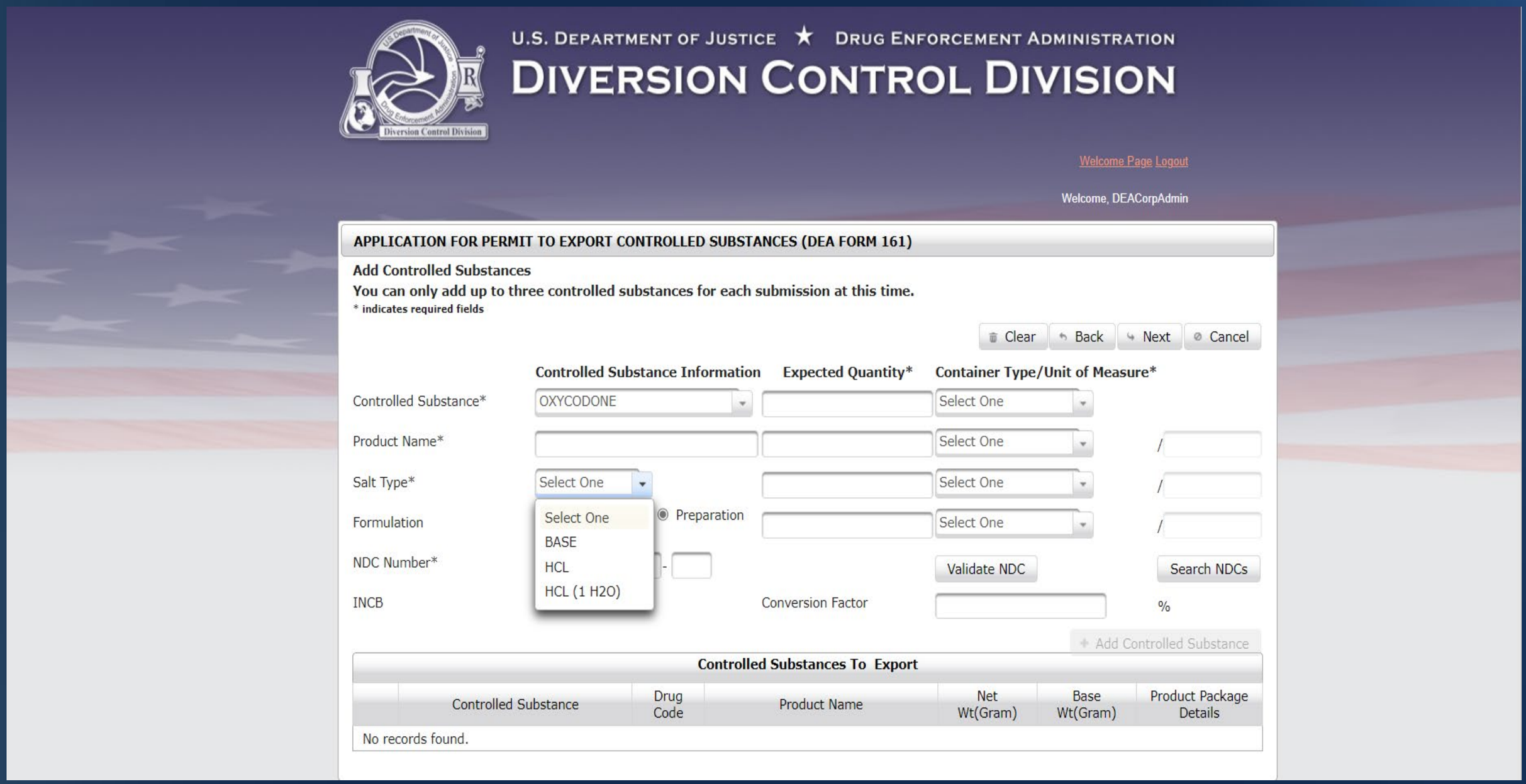

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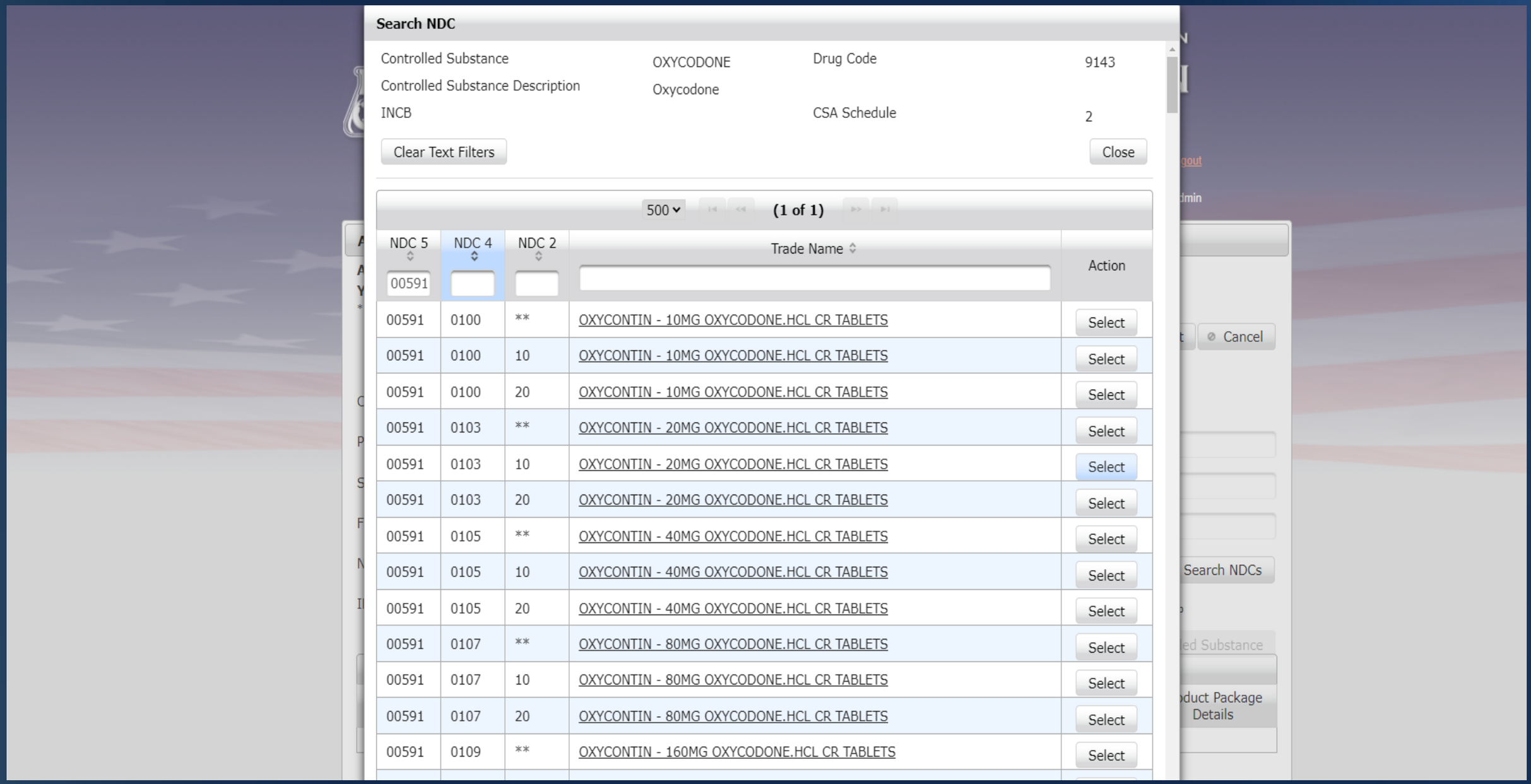

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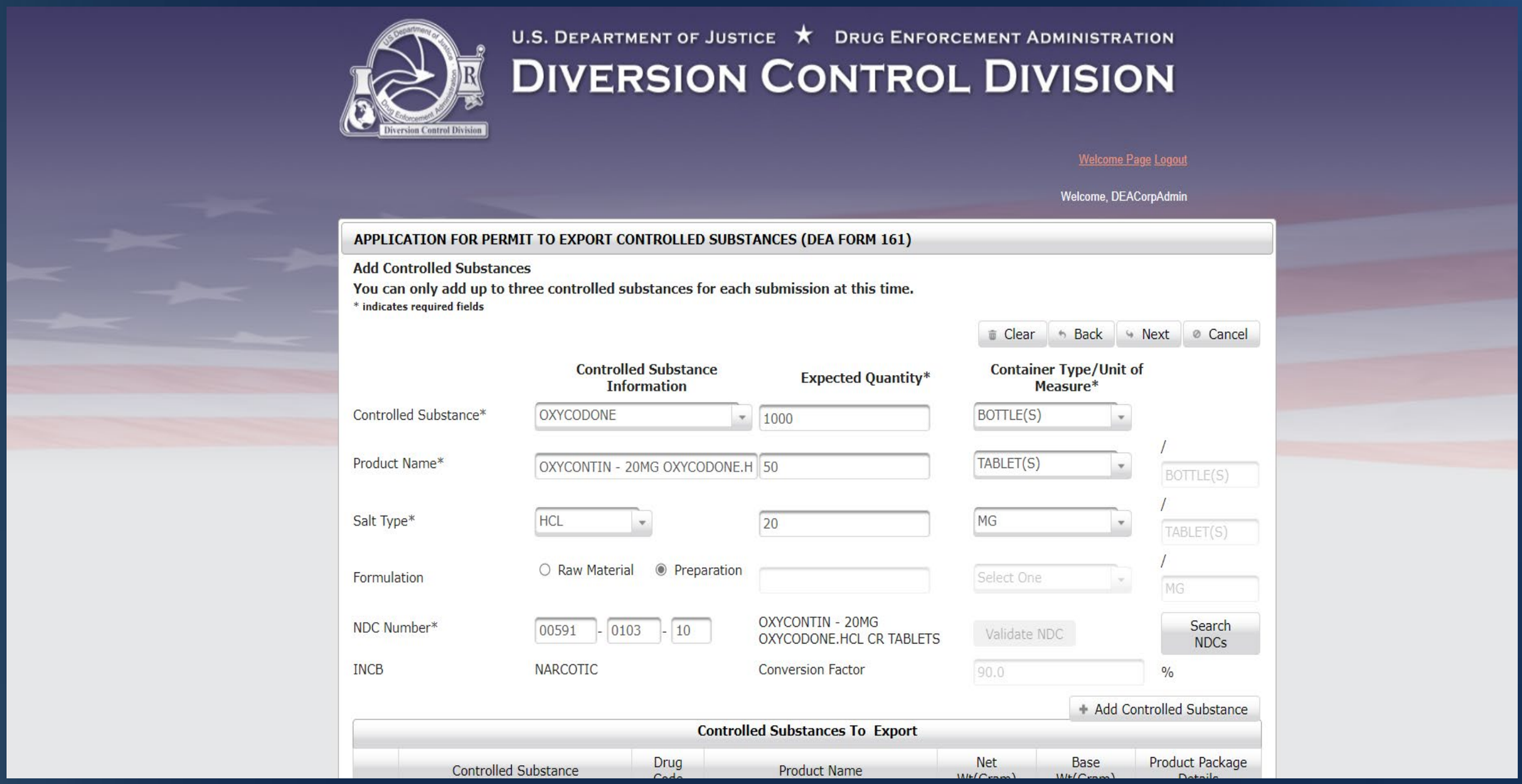

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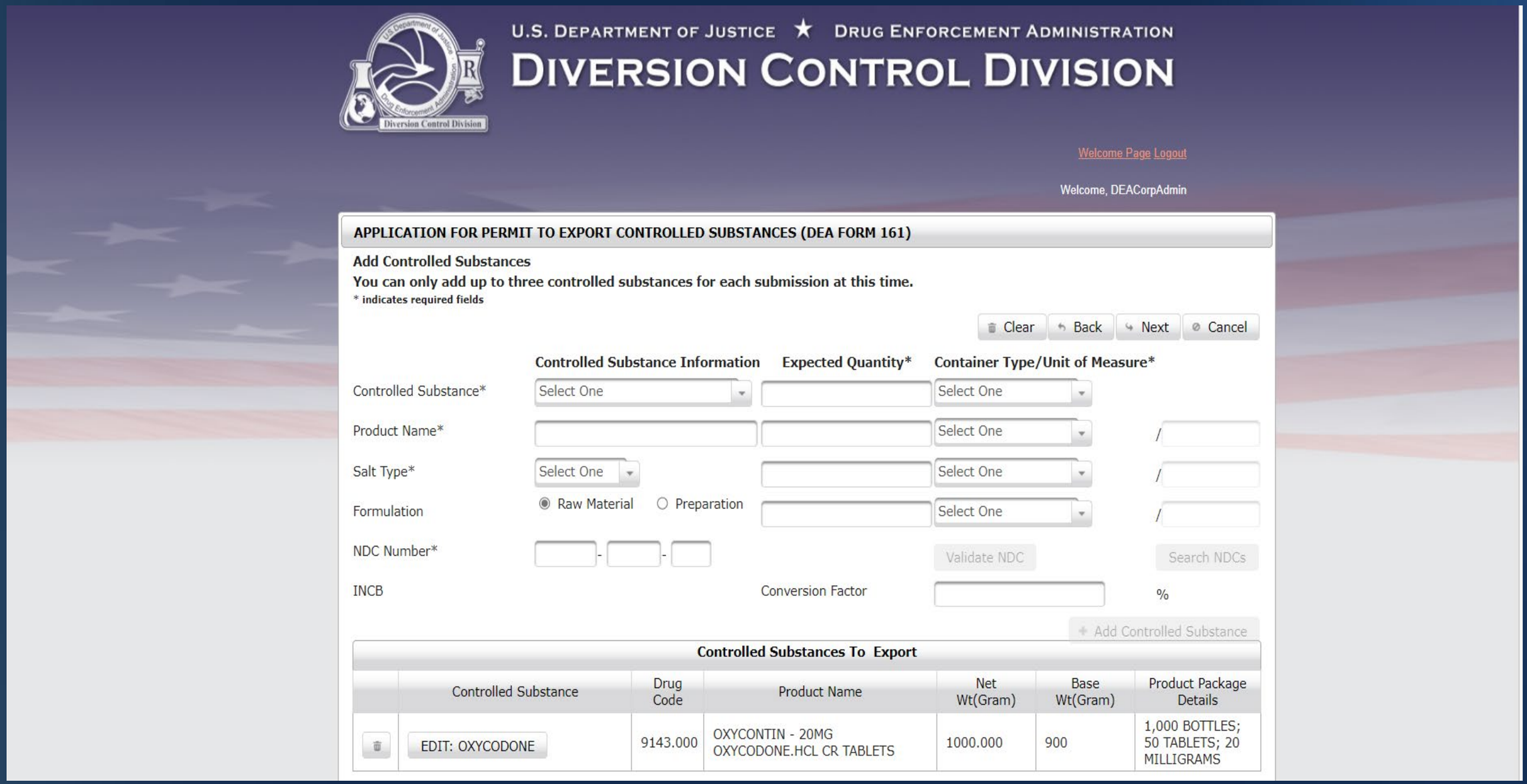

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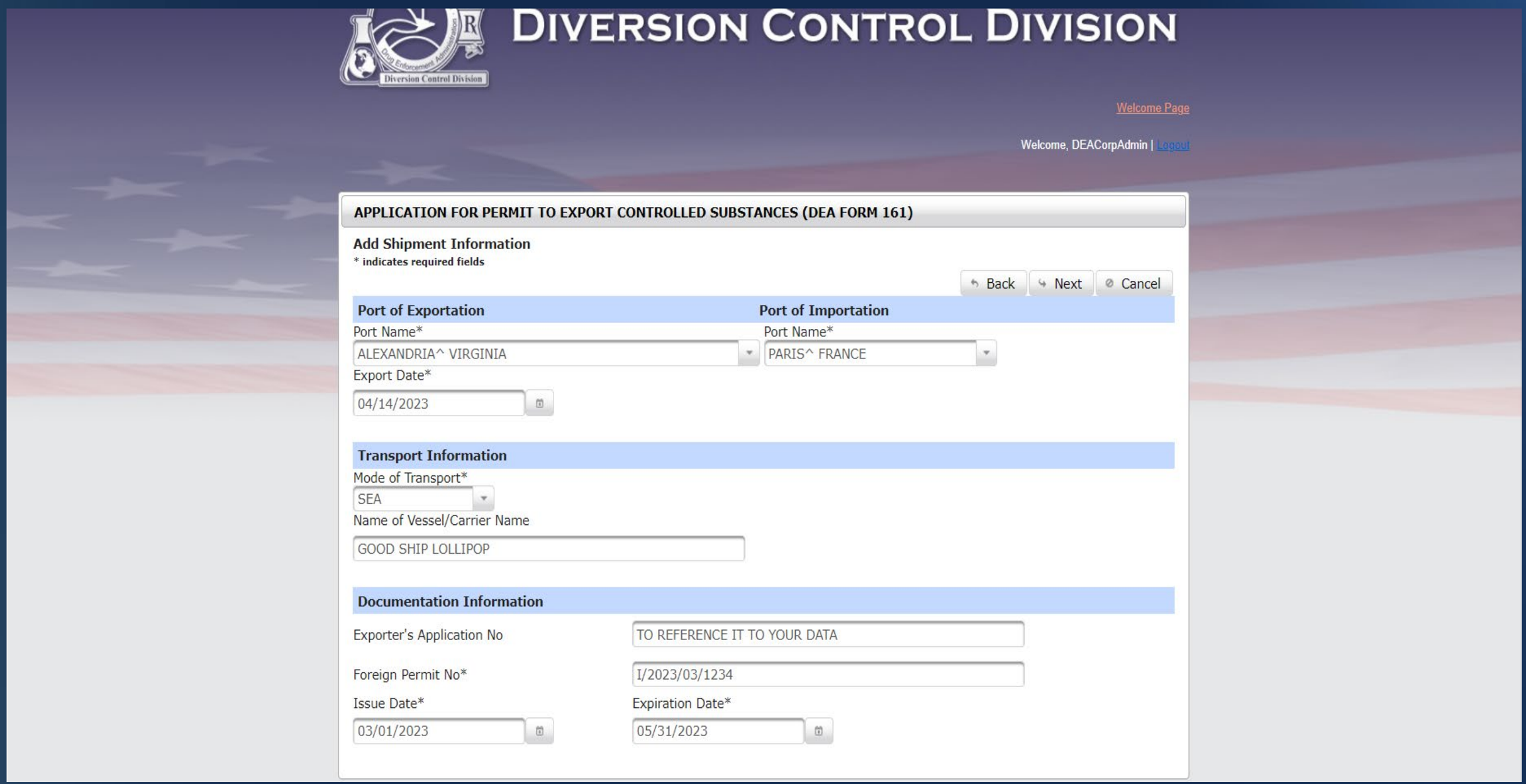


Online IMEX (Import & Export)

APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161)

*Please confirm all information before submitting this declaration. To make changes, click on the corresponding header label.

Submit | Cancel

Exporter

DEA-DRGI-TEST
600 ARMY NAVY DR
ARLINGTON, VA 22202
DEA Number: RD0445379

Edit Foreign Consignee

THE TOM THUMB COMPANY
600 STRAIT ST
PARIS, FRANCE ABC-1234

Edit Controlled Substances To Export

Controlled Substance	Drug Code	Product Name	Net Wt (Gram)	Base Wt (Gram)	Product Package Details
OXYCODONE	9143.000	OXYCONTIN - 20MG OXYCODONE.HCL CR TABLETS	1000.000	900	1,000 BOTTLES; 50 TABLETS; 20 MILLIGRAMS

Edit Port of Exportation

Port Name: ALEXANDRIA VIRGINIA
Date: 04/14/2023

Edit Port of Importation

Port Name: PARIS FRANCE

Edit Transport Information

Mode of Transport: SEA
Name of Vessel/Carrier Name: GOOD SHIP LOLLIPOP

Edit Documentation Information

Exporter's Application No: TO REFERENCE IT TO YOUR DATA
Foreign Permit No: I/2023/03/1234
Issue Date: 03/01/2023
Expiration Date: 05/31/2023

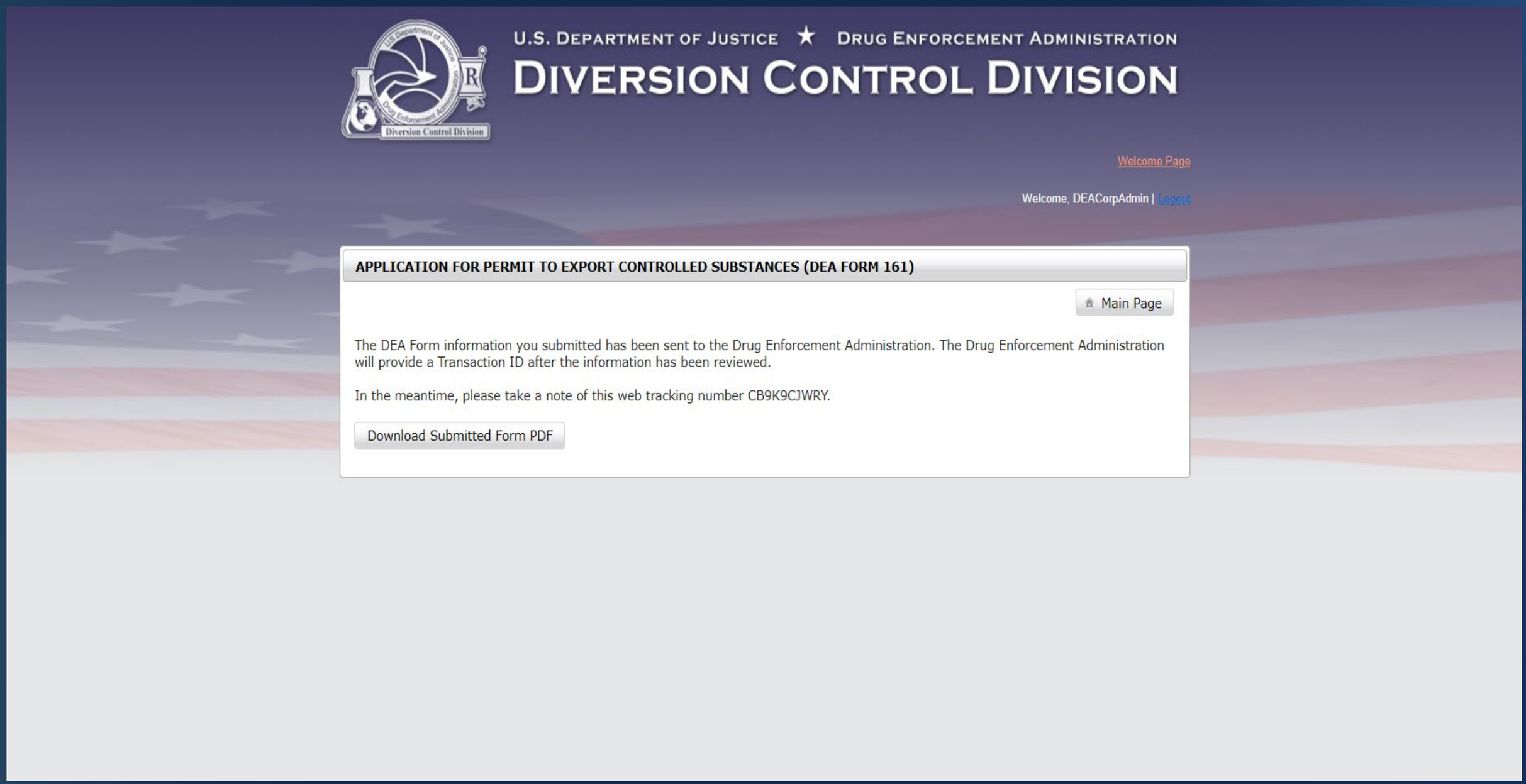
Certification

☑ I certify the controlled substances listed herein are necessary and intended for medical or scientific needs in the country of import and will not be re-exported therefrom; and the information I'm providing to the Drug Enforcement Administration is, to the best of my knowledge and belief, complete and accurate.

☑ The packages to be exported are labeled in conformance with 21 C.F.R. Part 302 and, to the best of my knowledge and belief, the importing country has instituted and maintains a system for the control of these substances; the drugs are consigned to a holder of such permits or licenses as may be required under the laws of the country of import; the substances are to be applied exclusively to medical or scientific uses within the country of import; there is an actual need for the controlled substances for medical or scientific uses within such country; the substances will not be re-exported therefrom; except, in the case of bulk cocaine alkaloid, the substance will be processed within the country of import and the products therefrom may be re-exported in accordance with Paragraph 2, Article 31 of the Single Convention on Narcotic Drugs, 1961.

Authorized Individual	Submit Date	Name of Firm and Telephone Number
MARK VIA	03/29/2023	DEA-DRGI-TEST

Online IMEX (Import & Export)



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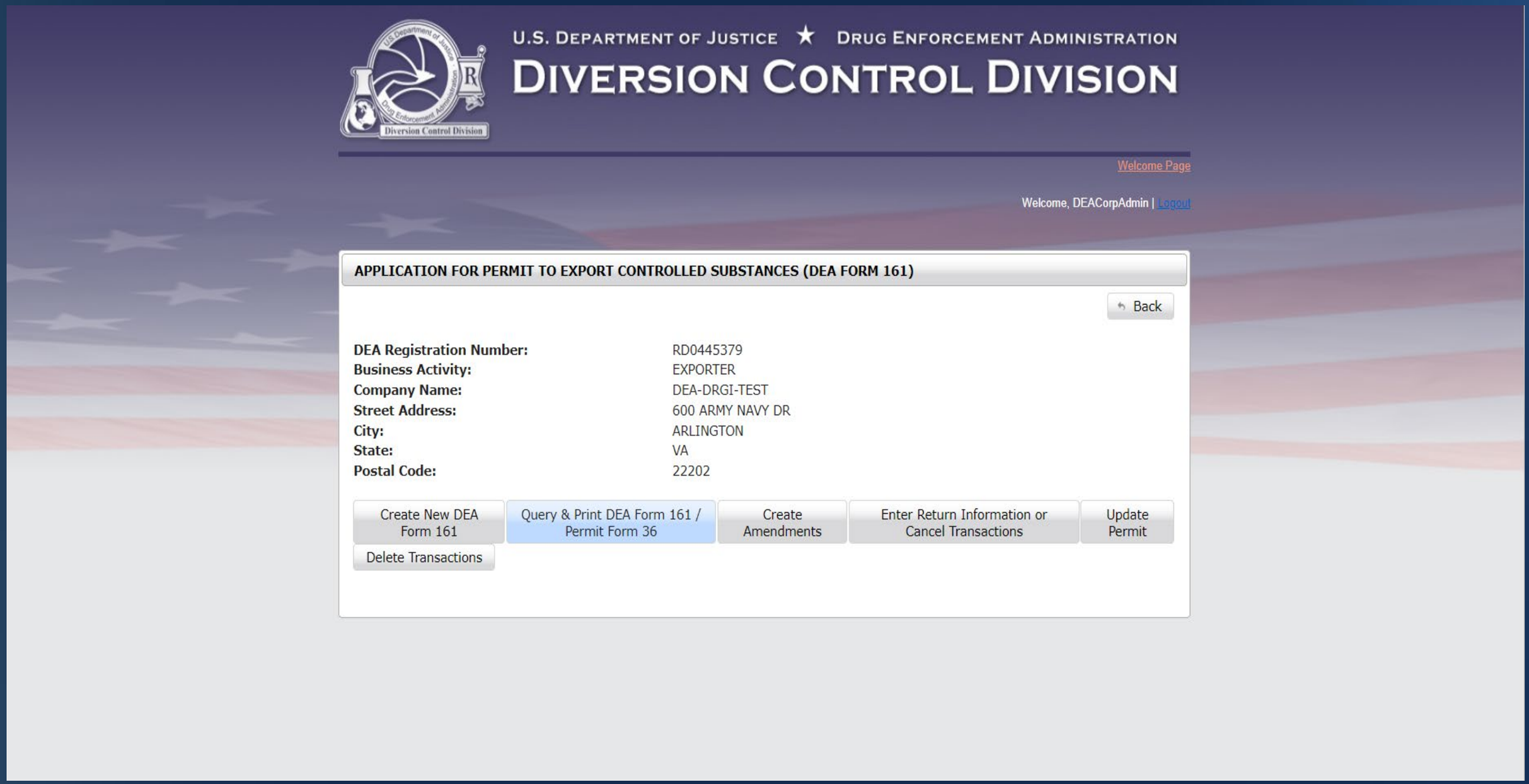

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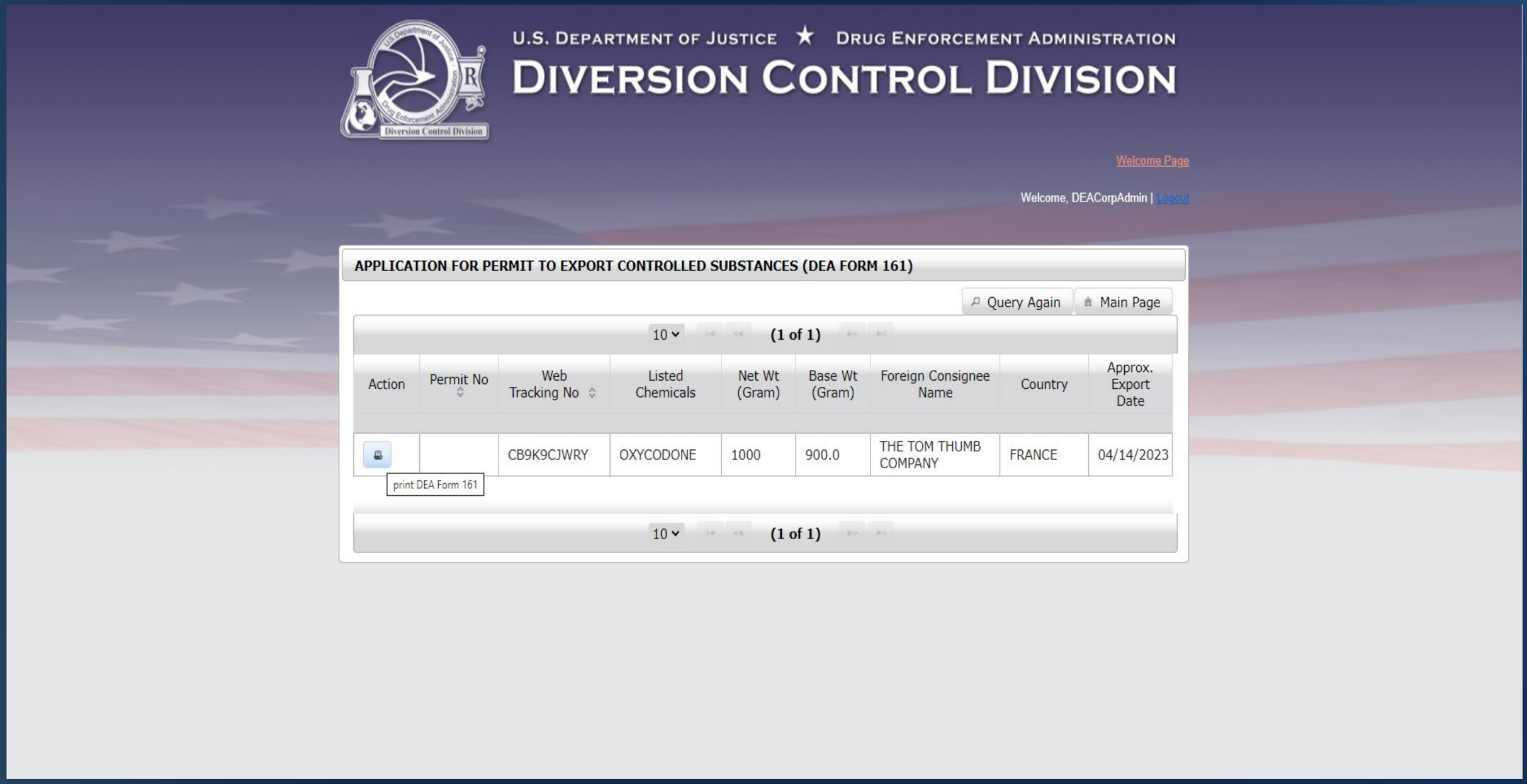


Imports & Exports

The Import and Export Section (DRI) requires some forms to be e-mailed for the following situations:

- No standard conversion to base*
- Schedule V substances without an official drug code
- Amphetamine Combination Salts Drug Products
- Re-exports within and outside of the EEA

No Standard Conversion Factor

Memorandum

Subject	Date
Control Status of 2-(5-methoxy-1H-indol-3-yl)-N,N-bis(methyl-d3)ethan-1-amine-1,1,2,2-d4 fumarate	December 20, 2022

To

Aziz Elkholy, Chief
Import/Export Section
Diversion Control Division

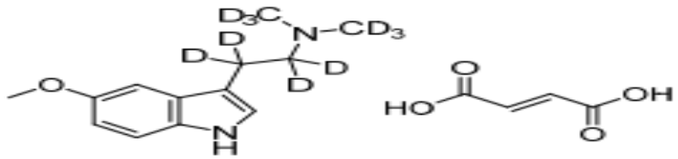
From TLB

Terrence L. Boos, Ph.D., Chief
Drug and Chemical Evaluation Section
Diversion Control Division

This memo is in response to a request from DRI on November 16, 2022, to evaluate the control status and calculate a conversion factor for 2-(5-methoxy-1*H*-indol-3-yl)-*N*,*N*-bis(methyl-d_3)ethan-1-amine-1,1,2,2-d_4 fumarate (5-MeO-DMT-d_{10} fumarate). DOE conducted a scientific analysis of the chemical structure of this substance in accordance with the definitions within the Controlled Substances Act (CSA) and its implementing regulations. Based on this review, DOE determined that 5-MeO-DMT-d_{10} fumarate is a schedule I controlled substance under the CSA.

Title 21 of the Code of Federal Regulations (CFR) § 1308.11(d)(15) controls 5-MeO-DMT and its salts, isomers, and salts of isomers in schedule I. The CSA does not distinguish isotopically labeled compounds, and deuterated 5-MeO-DMT is treated the same as 5-MeO-DMT. 5-MeO-DMT-d_{10} fumarate is assigned the Controlled Substances Code Number (CSCN) 7431, which is that of 5-MeO-DMT. The conversion factor (CF) for 5-MeO-DMT-d_{10} fumarate to 5-MeO-DMT base is 0.6338.

The chemical structure used to make this determination is shown below.



2-(5-methoxy-1*H*-indol-3-yl)-*N*,*N*-bis(methyl-d_3)ethan-1-amine-1,1,2,2-d_4 fumarate
schedule I
CSCN: 7431
CF: 0.6338

Schedule V substances

SUBSTANCE	CSCN	CSA SCH	NARC	OTHER NAMES
Remimazolam (4H-imidazol[1,2-a][1,4]benzodiazepine-4-propionic acid)	2846	IV	N	8-bromo-1-methyl-6-(2-pyridinyl)-(4S)-methyl ester, benzenesulfonate (1:1) and also, methyl 3-[(4S)-8-bromo-1-methyl-6-pyridin-2-yl-4H-imidazo[1,2-a][1,4]benzodiazepin-4yl]propanoate benzenesulfonic acid
Serdexmethylphenidate	1729	IV	N	
Sibutramine	1675	IV	N	Meridia
Solriamfetol (2-amino-3-phenylpropyl car-bamate; benzenepropanol, beta-amino-, carbamate (ester))	1650	IV	N	
SPA	1635	IV	N	1-dimethylamino-1,2-diphenylethane, Lefetamine
Suvorexant	2223	IV	N	MK-4305, [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone
Temazepam	2925	IV	N	Restoril
Tetrazepam	2886	IV	N	Myolastan, Musaril
Tramadol (2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol)	9752	IV	Y	Tramadol
Triazolam	2887	IV	N	Halcion
Zaleplon	2781	IV	N	Sonata
Zolpidem	2783	IV	N	Ambien, Ivadal, Stilnoct, Stilnox
Zopiclone	2784	IV	N	Lunesta
Brivaracetam	2710	V	N	BRV, UCB-34714, Briviact, ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide)
Cenobamate [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl]carbamate	2720	V	N	2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester)
Codeine preparations - 200 mg/(100 ml or 100 gm)		V	Y	Cosanyl,Robitussin A-C,Cheracol,Cerose,Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du		V	Y	Motofen
Dihydrocodeine preparations 100mg/(100 ml or 100 gm)		V	Y	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4		V	Y	Lomotil, Logen
Ethylmorphine preparations 100 mg/(100 ml or 100 gm)		V	Y	
Ezogabine	2779	V	N	Potiga
Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one)	2401	V	N	
Lacosamide	2746	V	N	Vimpat
Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]	2790	V	N	Reyvow
Opium preparations - 100 mg/(100 ml or 100 gm)		V	Y	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pregabalin	2782	V	N	Lyrica
Pyrovalerone	1485	V	N	Centroton, Thymergix

Amphetamine Combination Salts

Amfetamine	Acetylsalicylate		42.9
	Adipate		48.1
	Aspartate		50.4
	Aspartate monohydrate	851591-76-9	64.2
	Bitartrate		47.0
	Hydrochloride	27-06-50-5	79.2
	Para-aminophencylacetate		47.2
	Parachlorophenoxyacetate		42.0
	Pentobarbiturate		37.4
	Phosphate (1 mol. base)	139-10-6	58.0
	Phosphate (2 mol. base)		73.4
	Resinate		—
	Sulfate (2 mol. base)	60-10-6	73.4
	Tannate		29.6
	Tartrate (2 mol. base)		64.3

Amphetamine Combination Salts

Dexamfetamine	Adipate		48.1
	Carboxymethylcellulose		—
	Hydrochloride	1462-73-3	79.2
	Pentobarbiturate		37.4
	Phosphate (2 mol. base)		73.4
	Phosphate	7528-0-9	58.0
	Resinate		—
	Saccharate (monobasic)		39.1
	Sulfate (2 mol. base)	51-63-8	73.4
	Tannate		29.6
	Tartrate		47.4

Re-Exports

Controlled Substances Export Reform Act (2005)

- From the US to a 1st country; from the 1st country to one or more 2nd countries; No re-export from the 2nd countries
- The DEA-161-R is required; Information concerning the consignees of re-export must be provided to the DEA on the initial submission
- Re-exports from the 1st country to the 2nd must occur within 180-days after departure from the US

Re-Exports

Improving Regulatory Transparency for New Medical Therapies Act (2015)

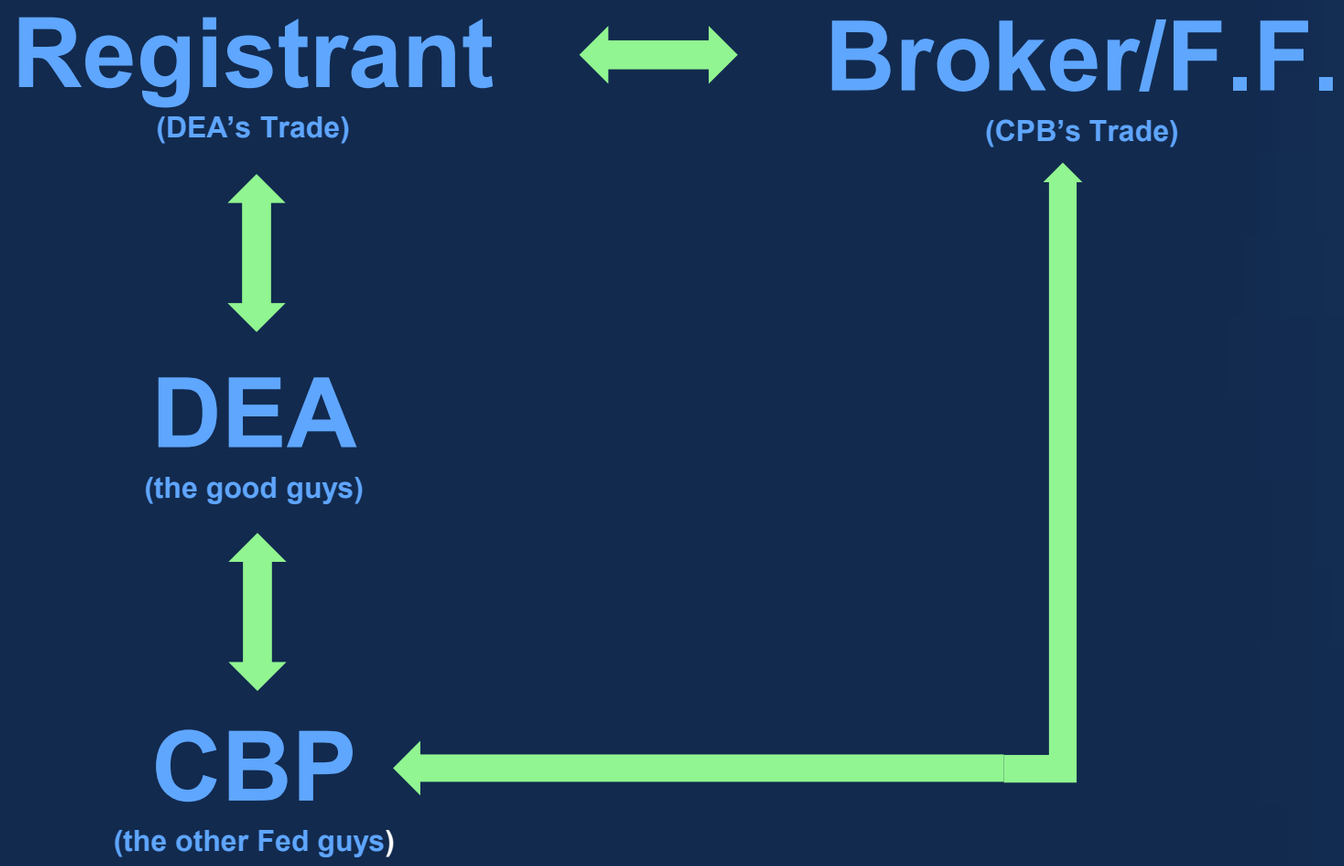
- From the US to an EEA country; from the 1st EEA country to other EEA countries; unlimited re-export within the EEA; cannot re-export outside of the EEA
- The DEA-161-R application is required in lieu of a DEA-161-R-EEA; Use EEA Countries for re-export destination; Information concerning the consignees of re-export must be provided to the DEA with the Return Information

Re-Exports

Improving Regulatory Transparency for New Medical Therapies Act (2015)

- By law, there is no time limit for re-exports
- The 1st country must always be an EEA country
- The EEA includes EU countries and also Iceland, Liechtenstein, and Norway. Switzerland and the UK are not members of the EU or EEA

Imports & Exports



Imports & Exports

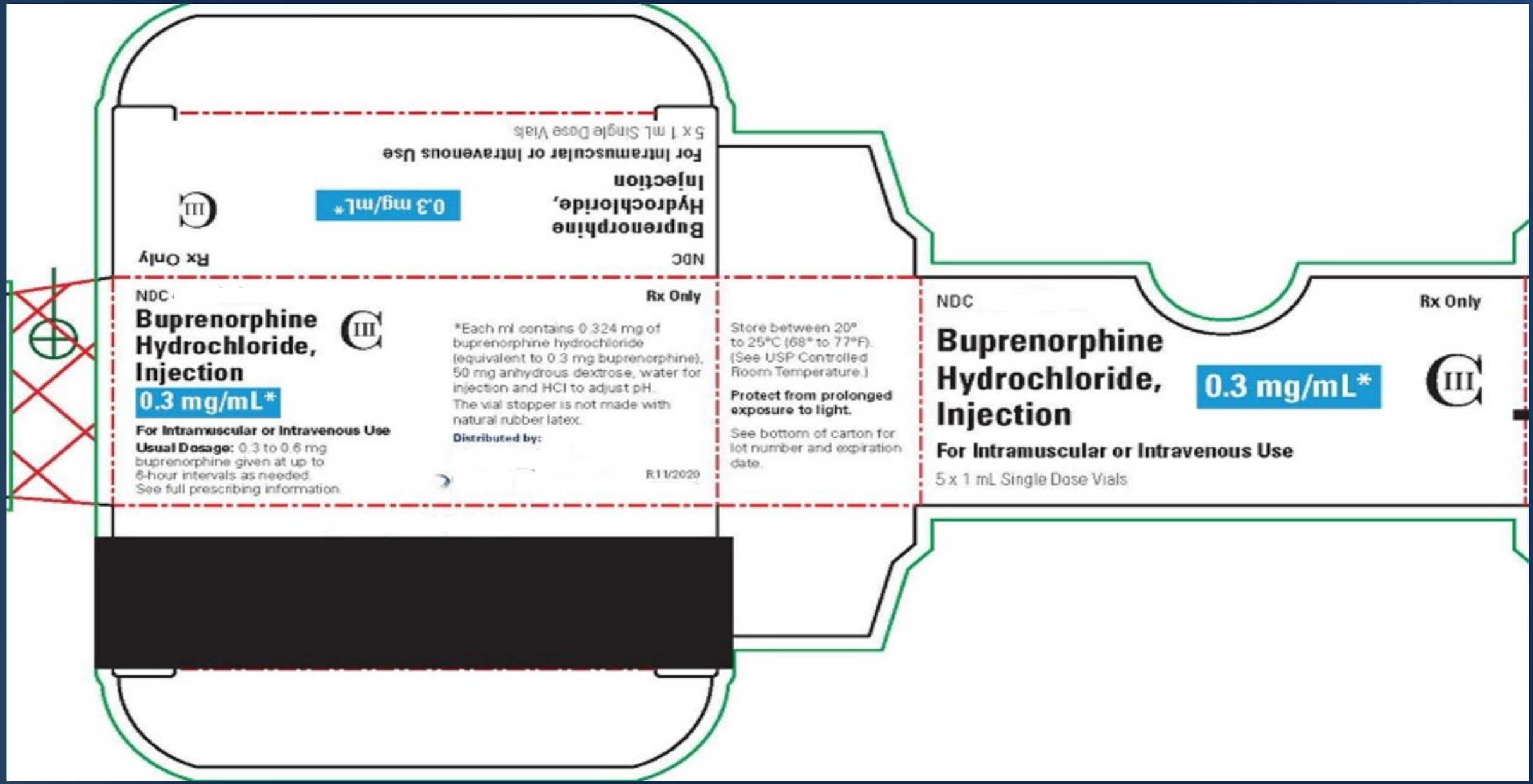
The crucial ITDS/ACE data:

- DEA Registration #
- Permit #/Transaction ID #
- Drug Code
- Base Weight & Unit of Measure (UOM)

Issues

- Uploading a foreign import permit or LONO that is not issued by the Competent National Authority (CNA); i.e. the Central Bureau of Narcotics, not the CDSCO, is the CNA of India
- Incorrect use of base/salt relative to the NDC #
- Importing or Exporting on the same day the DEA authorized your application or declaration
- Providing Return Information prior to the shipment departing the US

Base/Salt Example



Issues

- DRI has to review each uploaded attachment. Please label PDF uploads (permit, LONO, etc.) and don’t upload extraneous information
- Provide your reference number, permit #, tracking #, in the subject line of any e-mails you send to DRI
- Provide your DEA Registration # and your telephone number in your e-mail if you need DRI to resolve an issue
- The DEA approved my prior submission

Issues

- If you have an importer or exporter registration for controlled substances, that registration cannot be used to import or export Ephedrine, Pseudoephedrine, Phenylpropanolamine API or bulk finished dosage forms; Per the regulations, the dosage units must be in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Check the INCB Status of Estimates and Status of Assessments at www.INCB@org

Issues

- If you submit an application or declaration and DRI has approved it, and you later submit an amendment to the original, then by regulation you must use the amended DEA permit or declaration; the DEA permit or declaration must accompany the shipment