

Underwritten by Scottsdale Insurance Company
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1-800-423-7675 • A Stock Company

PANDEMIC AND EPICDEMIC COUNTERMEASURE PRODUCTS AND SERVICES SUPPLEMENTAL APPLICATION

This application is in addition to the Life Science Liability Application required when applying for coverage. This supplemental application is specific to pandemic and epidemic countermeasure products used to treat, diagnose, cure, prevent or mitigate COVID-19, SARS-COV-2 or a mutating virus and related professional services.

Please complete all sections that pertain to the products and services that are part of your product or service offering.

LEGAL NAME OF FIRST NAMED INSURED:

SECTION 1. PHARMACEUTICALS/BIOLOGICS/VACCINES: Please complete the following and provide a description of						
products and related revenue expected. Section Not Applicable						
TYPE OF PRODUCT:	PRODUCT HAS ACI	HIEVED:	YOUR ORGANIZATION	N IS A:		
NDA Pharmaceutical	☐ Investigational Use Authorization	☐ Emergency Use Authorization	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
ANDA Pharmaceutical	☐ Investigational Use Authorization	☐ Emergency Use Authorization	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Biological Product/Serum	☐ Investigational Use Authorization	☐ Emergency Use Authorization	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Vaccine	☐ Investigational Use Authorization	☐ Emergency Use Authorization	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						

SECTION 2. PERSONAL PROFECTIVE EQUIPMENT (PPE): Please complete the following and provide a description of products and related revenue expected. \Box Section Not Applicable

TYPE OF PRODUCT:	FDA EMERGENCY (JSE AUTHORIZATION	PLEASE COMPLETE YO	OUR ORGANIZATION TY	PE:	
NIOSH-Approved Air Purifying Respirators- Medical Use	☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
NON-NIOSH-Approved Air Purifying Respirators- Medical Use	☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Non-Surgical Face Masks Intended-Medical Use	☐ Filed for EUA☐ Not Filing	☐ Received EUA☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Surgical Face Shields- Medical Use	☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Surgical Masks Intended to Provide Liquid Barrier Protection-Medical Use	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Gowns, Other Apparel and Glove-Medical Use	☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Other:	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Other:	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						

TYPE OF PRODUCT:	FDA EMERGENCY	USE AUTHORIZATION	PLEASE COMPLETE YO	UR ORGANIZATION TYP	E:	
Ventilators	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Anesthesia gas machines	☐ Filed for EUA☐ Not Filing	☐ Received EUA☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Positive Pressure Breathing Devices	☐ Filed for EUA☐ Not Filing	☐ Received EUA☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Ventilator Tubing Connectors and/or Accessories	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Extracorporeal Blood Purification Devices, Membrane Oxygenation and Cardiopulmonary Bypass Devices	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Diaphragmatic Pacing Therapy System	☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Ophthalmic Assessment and Monitoring Devices	☐ Filed for EUA☐ Not Filing	☐ Received EUA☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						
Other:	☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
List all countermeasure products and expected 12-month revenue:						

Ust all countermeasure products, explanation and expected 12-month revenue:	SECTION 4. INVITRO DIAGNOSTICS/TEST KITS: Please describe the type of test, technology of the test and how this						
claim to have specific performance characteristics. Section Not Applicable NPE OF PRODUCT:		•			•		•
Rit Type:	·				•	ine specimen typ	es for writer you
Filed for EUA Received EUA Manufacturer Us or Foreign Us or Foreign Other:	TYPE OF PRODUCT:	FDA EMERGENCY	USE AUTHORIZATION	PLEASE COMPLETE YO	OUR ORGANIZATION TYP	PE:	
Products, explanation and expected 12-month revenue:	Kit Type:			_	_		☐ US or ☐ Foreign Other:
Field for EUA Received EUA Manufacturer U.S.or Foreign Distributor Other:	products, explanation and						
Proceed 12-month revenue:	Kit Type:			•	_		☐ US or ☐ Foreign Other:
Filed for EUA Received EUA US or Foreign US or Foreign US or Foreign Other: Foreign US or Foreign Other: Other:	products, explanation and						
products, explanation and expected 12-month revenue: Attached a separate document if more space is needed. 4.a. Will you be providing only parts and components of test kits? (Ex. nasopharyngeal/ oropharyngeal swabs) Please provide a list using the following. TYPE OF PRODUCT: FDA EMERGENCY USE AUTHORIZATION PLEASE COMPLETE YOUR ORGANIZATION TYPE: Flied for EUA Received EUA US or Foreign US or Foreign US or Foreign Distributor Other: List all countermeasure Products and expected 12-month revenue: Filed for EUA Received EUA US or Foreign US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign Other: List all countermeasure Filed for EUA Received EUA US or Foreign Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure Filed for EUA Received EUA Other: List all countermeasure	Kit Type:			_	_		☐ US or ☐ Foreign Other:
4.a. Will you be providing only parts and components of test kits? (Ex. nasopharyngeal/ oropharyngeal swabs) Please provide a list using the following. TYPE OF PRODUCT:	products, explanation and						
Please provide a list using the following. TYPE OF PRODUCT:	Attached a separate docume	ent if more space	is needed.				
Please provide a list using the following. TYPE OF PRODUCT:							
Filed for EUA Received EUA US or Foreign US or Foreign Other:	·		•	ents of test kits? (Ex. nasopharynge	eal/ oropharynge	al swabs)
Not Filing Not Required Manufacturer CMO Distributor Other:	TYPE OF PRODUCT:	FDA EMERGENCY	USE AUTHORIZATION	PLEASE COMPLETE YO	OUR ORGANIZATION TYP	PE:	
products and expected 12-month revenue: Filed for EUA				•	_		☐ US or ☐ Foreign Other:
Not Filing Not Required Manufacturer CMO Distributor Other:	products and expected						
products and expected 12-month revenue: Filed for EUA				_		_	☐ US or ☐ Foreign Other:
□ Not Filing □ Not Required Manufacturer CMO Distributor Other: List all countermeasure products and expected 12-month revenue: Attached a separate document if more space is needed. 4.b. Will you provide any RT-PCR Instruments, software, automated extraction instruments □ YES or □ NO	products and expected						
Attached a separate document if more space is needed. 4.b. Will you provide any RT-PCR Instruments, software, automated extraction instruments □ YES or □ NO				_	_	_	☐ US or ☐ Foreign Other:
4.b. Will you provide any RT-PCR Instruments, software, automated extraction instruments ☐ YES or ☐ NO	products and expected						
	Attached a separate document if more space is needed.						
or other products/ services related to your test kit products or independently?							

4.c.	Will you provid	e laboratory and analysis of the tests? $\ \square$ YES or $\ \square$ NO					
4.d.		and related products cleared, CLIA waived, approved, or subject to an approved $\ \square$ YES or $\ \square$ NO ional device exemption?					
4.e.	•	•	complexity labor tics for viral path	ratory with experiogens?	ience developing	and	☐ YES or ☐ NO
4.f.	Please supply the EUA INTERACTIVE REVIEW COMPLETED TEMPLATE FOR MOLECULAR-BASED TESTS FOR SARS-CoV-2 THAT CAUSES CORONAVIRUS DISEASE 2019 (COVID-19) AND THE REGULATORY APPROVAL/CLEARANCE STATUS LETTER for all submissions with test kits.						
			ed. Section N	VICES: Please com ot Applicable	iplete the followi	ng and provide a	description of
TYPE OF F	PRODUCT:	FDA EMERGENCY	USE AUTHORIZATION	PLEASE COMPLETE YO	UR ORGANIZATION TYP	E:	
Infusion Accessor	Pumps or ies	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
	all countermeasure oducts and expected 12-month revenue:						
Clinical E Thermor	lectronic meters	☐ Filed for EUA☐ Not Filing	☐ Received EUA☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
	all countermeasure oducts and expected 12-month revenue:						
	s, Disinfectant Air Purifiers	☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
	all countermeasure oducts and expected 12-month revenue:						
Other:		☐ Filed for EUA ☐ Not Filing	☐ Received EUA☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
	all countermeasure oducts and expected 12-month revenue:						
Other:		☐ Filed for EUA☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
	all countermeasure oducts and expected 12-month revenue:						
Other:		☐ Filed for EUA ☐ Not Filing	☐ Received EUA ☐ Not Required	☐ US or ☐ Foreign Manufacturer	☐ US or ☐ Foreign CMO	☐ US or ☐ Foreign Distributor	☐ US or ☐ Foreign Other:
	all countermeasure oducts and expected 12-month revenue:						

SECTIO	ON 6. CLINICAL TRIA	LS □ Section Not Appli	cable				
6.a.	Are you conducting clinical trials for countermeasure products?						
6.b.	Are all clinical trials being conducted in accordance with FDA regulation and oversight?						
6.c.	Will any clinical trials	s include pregnant wom	en or children under the age of 18?	\square YES or \square NO			
6.d.		nical trial data is provid	spreadsheet and provide all related inf ed in the main application, please spec	· ·			
SECTIO	ON 7. EMERGENCY U	JSE AUTHORIZATION					
7.a.	provide this product	and service after the pu	rketing of your device. Will you be contublic health emergency is terminated? val plan in a separate document.	tinuing to \square YES or \square NO			
7.b.			USE AND INVESTIGATIONAL USE AUT N REGULATORY BODIES REGARDED AS				
SECTIO	ON 8. DEFENSE PRO	TECTION ACT					
8.a.	Are any of the products or services authorized and mandated to be provided by a governmental entity pursuant to the Defense Protection Act? If yes, please provide a copy of the contract and specify the products/services:						
SECTIO	ON 9. GENERAL QUE	STIONS					
9.a.	Are any of these products or activities new to your organization? \Box YES or \Box NC Please specify the products that are new:						
9.b.	•		e countermeasure products and service ce, business plan and financial proforma in a se				
9.c.	If any of the products are being imported to the US from a foreign manufacturer, please provide the name manufacturer(s), country and FDA status.						
Manuf	acturer Name	Product(s)	Address	FDA Regulatory Status			
	•	•	II parties in the supply chain? vide a reason for all that you do not have a con	☐ YES or ☐ NO tract.			
9.d.		de sterilization services	• •	\square YES or \square NO			

9.e.	Do you need to decontamination any products being imported per FDA requirements? $\ \square$ YES or $\ \square$ NO If yes, please describe compliance measures.							
9.f.	Do you plan to rent or service any countermeasure product? $\ \square$ YES or $\ \square$ NO If yes, please describe compliance measures.							
9.g.	Please provide an <u>actual</u> picture of any product(s) and the associated labeling, warranties and representations and direction for us in a separate document.							
9.h.			mental contracts to provide counterm Act? If yes, please attach a copy of the	-				
Contr	act Parties	Product(s)	Production Requirements	Delivery Date Requirement				
9.i.	Are you in compliance does not require FDA a Please describe all complian	authorization?	empliance requirements if your produc	ct ☐ YES or ☐ NO				
9.j.	Do you have standard and/or disposal?	operating procedures in p	lace to track all products for recovery	☐ YES or ☐ NO				
	•	plan in place for removal to do so for regulatory co	and destruction of the product(s) fron mpliance?	n the □ YES or □ NO				
FCTIO	N 10 SIGNATURE ACKN	OWI FOGEMENT AND CER	RTIFICATION					

THE APPLICANT REPRESENTS THAT THE STATEMENTS AND FACTS MADE IN THIS APPLICATION ARE TRUE AND THAT NO MATERIAL FACTS HAVE BEEN SUPPRESSED OR MISSTATED.

Applicant acknowledges a continuing obligation to report to us as soon as practicable any material change in the facts and statements above, and in each supplementary application, for which applicant becomes aware after signing the application.

Completion of this form does not bind coverage. Applicant's acceptance of Company's quotation is required prior to binding coverage and policy issuance. It is agreed that this form shall be the basis of the contract should a policy be issued.

The Applicant hereby declares that the above statements and particulars are true and the Applicant agrees that this application shall be the basis of the contract with the insurance company.

I/We hereby declare that the above statements and particulars are true and I/We agree that this application shall be the basis of the contract with the insurance company.

FRAUD WARNING: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. (Not applicable in AL, AR, CO, DC, FL, KS, KY, LA, ME, MD, MN, NE, NJ, NY, OH, OK, OR, RI, TN, VA, VT or WA.)

NOTICE TO ALABAMA APPLICANTS: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or who knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution fines or confinement in prison, or any combination thereof.

NOTICE TO COLORADO APPLICANTS: It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance, and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policy holder or claimant for the purpose of defrauding or attempting to defraud the policy holder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

WARNING TO DISTRICT OF COLUMBIA APPLICANTS: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

NOTICE TO FLORIDA APPLICANTS: Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony of the third degree.

NOTICE TO KANSAS APPLICANTS: Any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written, electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

NOTICE TO KENTUCKY APPLICANTS: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime.

NOTICE TO MAINE APPLICANTS: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties may include imprisonment, fines or a denial of insurance benefits.

NOTICE TO MARYLAND APPLICANTS: Any person who knowingly or willfully presents a false or fraudulent claim for payment of a loss or benefit or who knowingly or willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

NOTICE TO MINNESOTA APPLICANTS: A person who files a claim with intent to defraud or helps commit a fraud against an insurer is guilty of a crime.

NOTICE TO NEW JERSEY APPLICANTS: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

NOTICE TO OHIO APPLICANTS: Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

NOTICE TO OKLAHOMA APPLICANTS: Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.

FRAUD WARNING (APPLICABLE IN ARKANSAS, LOUISIANA AND RHODE ISLAND): Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

FRAUD WARNING (APPLICABLE IN VERMONT, NEBRASKA AND OREGON): Any person who intentionally presents a materially false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

FRAUD WARNING (APPLICABLE IN TENNESSEE, VIRGINIA AND WASHINGTON): It is a crime to knowingly provide false, incomplete, or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines, and denial of insurance benefits.

NEW YORK FRAUD WARNING: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime, and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.

APPLICANT'S NAME AND TITLE:	
APPLICANT'S SIGNATURE:	DATE:
PRODUCER'S SIGNATURE:	
AGENT NAME:	AGENT LICENSE NUMBER: