



INSURANCE GROUP

| a Berkley Company

HEALTH, NUTRITION & LIFESTYLE APPLICATION

Applicant Name:

Agent's Name:

Mailing Address:

Mailing Address:

Location Address:

Proposed Effective Date:

From: 12:01 A.M. Standard Time at
the address of the Applicant
To:

Bankruptcy - Within the last 5 years, were there any pending or planned bankruptcies, or judgements for unpaid taxes against you, or your majority partner?

Yes No

Receivership – Within the last 5 years, has the property undergone or are there any plans for the property to undergo receivership?

Yes No

FEIN:

Applicant is: Individual Joint Venture LLC

Corporation Partnership Other – Specify:

Inspections and Audit Information:

Contact Name:

Title:

Phone Number:

Website:

Business Inception Date:

Please complete each section if applicable. If not applicable, check “N/A” and skip the entire section.

SECTION I – RISK PROFILE

1) If the Applicant is a Grower of Hemp or Cannabidiol (CBD), is Delta-9 THC content **more than 0.3%**? Yes No

(Note: If answered “Yes” to this question, this risk will be deemed ineligible and declined coverage.)

2) Provide the percentage of gross sales generated as an Importer – Directly Importing Ingredients or Finished Products. %

(Note: Applicants that have products drop shipped directly to customers without physical possession this risk will be deemed ineligible and declined coverage.)

3) Does the Applicant comply with the following requirements/industry standards:

a. Prop 65 labeling requirements? Yes No
(Note: If the answer to the above question is “No”, coverage will be deemed ineligible.)

b. cGMP? Yes No

4) Are the Applicant's operations performed at a residence? Yes No

5) Is Applicant controlled by, owned by, or commonly owned, affiliated or associated with any other organization? Yes No
 If Yes, confirm the legal entity name and operations of each, including organizational structure with ownership details:

SECTION II – ESTIMATED EXPOSURES

6) Confirm total sales of products, goods and services:

Annual Gross Sales:	Total	United States	Foreign
Next 12 Months	\$	\$	\$
Current Year	\$	\$	\$
Prior Year	\$	\$	\$

7) Provide a description of operations, list all products and goods, and advise if there have been any changes in products, goods, or operations within the last 12 months:

8) Provide the percentage of total gross sales generated by the following types of products (if none, enter 0):

	Upcoming Year (Estimate):	Prior Year (Actual):
a. Caffeine exceeding 300 mg per serving (all sources)	%	%
b. Cannabidiol (CBD)/hemp products	%	%
c. Hemp/CBD vaping devices and related accessories including cartridges & disposables	%	%
d. Class I & Class II Medical Products / Devices	%	%

9) Check all of the following products that the Applicant **will** make or sell, or **has** been made or sold in the past:

Nicotine / Tobacco Electronic Cigarettes	Hemp Vaping Devices	Cartridges/E-liquid
CBD Vape Oil	Replacement Batteries	Battery Rechargers
Blunts / Smokable Hemp	Cosmetics	

SECTION III – OPERATIONS

(In this section, check N/A if the Applicant does not perform the operations and the question doesn't apply. Do not complete questions in any section that is marked N/A and does not apply to the Applicant's operation.)

10) Any acquisitions of companies and operations in the past 5 years? Yes No N/A
 If Yes, list all:

11) Any Research and Development? Yes No N/A
 If Yes, provide details:

12) Does the Applicant operate retail store locations?	Yes	No	N/A
If Yes, how many?			
If any are in New York, provide the physical address:			
13) Does the Applicant contract out the manufacturing of their products to a third party?	Yes	No	N/A
If Yes, provide the manufacturer's name and physical address:			
14) Provide the percentage the Applicant's gross sales generated by the following types of operations:			
a. Manufacturer – Proprietary product formulas that are manufactured in the Applicant's facility			%
b. Contract Manufacturer – Products that are custom developed and formulated for third parties			%
c. Contract Manufacturer – Products for third parties that are based on the Applicant's proprietary formula, or solely to the specification of the customer's formula			%
d. Retailer (Own Label) – Products sold under the Applicant's own label or brand			%
e. Retailer/Distributor – Products of others sold/distributed on behalf of others			%
f. Extractor – Hemp or other			%
g. Grower - Hemp			%
h. Other (describe):			%
15) If the Applicant is a Manufacturer , confirm:	N/A		
a. Has or will use ingredients imported from foreign suppliers?	Yes	No	
If Yes, list the Countries of Origin:			
16) If the Applicant is a Contract-Manufacturer , Private/White Labeler – (Products that are custom developed and formulated for third parties and sold under third party labels / Products made based on Applicant's proprietary formula, or solely to the specification of the third-party customer formula and sold under third party customer labels), confirm if the Applicant:	N/A		
a. Is offering any product development or custom formulation services to third party customers?	Yes	No	
If Yes, confirm the credentials and experience of individuals signing off on formulation specifications:			
b. Is creating / designing original labels, warnings, instructions for use or other regulatory required wording for third party customers?	Yes	No	
If Yes, confirm the credentials and experience of individuals signing off on label specifications, including name of the law firm if one is used:			
c. Team has a minimum of three years of experience in the contract manufacturing, formulating, and labeling field?	Yes	No	

d. Is the Applicant certified cGMP compliant? If Yes, list the Accredited Certifying Body along with the date of certification:	Yes	No
If No, explain:		
e. What percentage of total sales are from products sold under labels of others?		%
f. Has written contracts or manufacturing agreements in place with clients?	Yes	No
If Yes, do they contain mutual indemnification wording?	Yes	No
g. Confirms that customers carry their own Product Liability coverage?	Yes	No
h. Confirms that customers have formal, written product recall procedures in place?	Yes	No
i. Provides Certificates of Analysis to customers upon delivery of the finished product?	Yes	No
j. Confirm the number of customers for whom the Applicant provides contract manufacturing services:		
17) If the Applicant is an Importer , confirm the following:	N/A	
a. List the countries of origin:		
b. Are all imported products and/or ingredients tested in the U.S. with proper quality assurance and quality controls?	Yes	No
c. Does the Applicant take physical possession of all products and/or ingredients directly imported to them?	Yes	No
18) If the Applicant is a Retailer (Own Label) or Retailer or Distributor (Label of Others) , provide the following information:	N/A	
a. Name and address of manufacturers/suppliers:		
b. List details on Quality Control/Quality Assurance in place:		
c. Are manufacturers/suppliers cGMP compliant?	Yes	No
d. Are agreements in place?	Yes	No
e. Are suppliers Certificates of Insurance obtained? If Yes, is the Applicant named as an Additional Insured?	Yes	No
f. Are inventory records kept?	Yes	No
g. Are there recall procedures in place by the Applicant or the manufacturer?	Yes	No
19) If the Applicant is performing Extraction/Processing , answer the following questions:	N/A	
a. Does the Applicant perform any extraction operations?	Yes	No
If No, provide the name and address of the company extracting and skip to question 20:		
If Yes, answer questions 19) b.- i.		
b. Will there be any residential operations?	Yes	No
c. What method of extraction will be used?		

d. Is the equipment commercial grade, certified and tested for its intended use, and operated by certified technicians or engineers? If No, who is operating and what experience do they have?	Yes	No
e. Will the hemp be tested for metals, pesticides, THC levels, and solvent residue?	Yes	No
f. What solvents will be used in the process?	Yes	No
g. Does the extraction facility comply with Class 1, Division 2 electrical requirements, state and local fire codes, and all regulations, laws and ordinances that involve the use, storage, handling and disposal of any gases used in the operations?	Yes	No
h. Is the extraction done in a fireproof contained area?	Yes	No
i. Is the Applicant the sole occupant of the building?	Yes	No
20) If the Applicant is a Grower , answer the following questions:	N/A	
a. Will operations include growing or cultivating in any of the following? (Check all that apply.)		
Indoor	Outdoor	Greenhouse
b. Does the Applicant have a license to grow hemp?	Yes	No
c. Are consumer products containing Hemp/CBD being sold?	Yes	No
d. Are customers provided with Certificates of Analysis to confirm product purity and the THC content?	Yes	No
e. Do farming operations include extraction on site?	Yes	No
21) If the Applicant manufactures or sells Class I & Class II Medical Products / Devices , confirm the following questions:	N/A	
a. Is the device used as a component part of someone else's end product / device? If Yes, list the Applicant's manufactured products that are a component of others end products / device:	Yes	No
b. Any past or present association with any of the products listed: <i>Latex Gloves, Breast Implants, Hip, Knee, Spinal Devices or Implants, DEHP, Pedicle Screws, IUD Devices Animal / Human Derived Products</i> ?	Yes	No
c. Does the Applicant hire licensed medical professionals to sell, design or offer instruction related to the use of the products?	Yes	No
d. Does the Applicant repair, install, or service any products?	Yes	No
e. Are Material Data Safety Sheets and Scheduled Maintenance Procedures issued to each customer?	Yes	No
SECTION IV – COSMETICS & SKINCARE	N/A	
22) Confirm if the Applicant complies with the following:		
a. Modernization of Cosmetics Regulation Act of 2022 (MoCRA)?	Yes	No
b. Cosmetic Safety Substantiation?	Yes	No
c. Adverse Event Recordkeeping and Serious Adverse Event Reporting?	Yes	No
d. Cosmetic Labeling and Fragrance Allergen Transparency Requirements?	Yes	No

23) Is the Applicant's facility is registered with the FDA?	Yes	No
24) Does the Applicant have a product listing? If Yes, list the products below, or attach:	Yes	No

25) Can the Applicant confirm that their products do NOT contain any Talc or PFAS (Perfluoroalkyl and Polyfluoroalkyl Substances)?	Yes	No
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SECTION V – HEMP & CANNABIDOL (CBD) N/A

26) Does the Applicant manufacture or sell any Hemp/Cannabidiol (CBD) products? If No, provide the name and address of the CBD Manufacturer and supplier:	Yes	No
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- a. Are batch records documenting the production details for each lot of finished products kept on file? Yes No
- b. If the products are certified to contain **no more than 0.3% Delta-9** THC, and has the product been tested and certified by a third-party laboratory? Yes No
- c. Is the certification of **no more than 0.3%** Delta-9 listed on the label? Yes No
- d. Are hemp or CBD products sourced from a licensed grower in the U.S.? Yes No
(Note: If answered "No", to 26) a-c., coverage for CBD will be unavailable.)

27) Are all of the cannabinoids contained in the products extracted from legally cultivated hemp?	Yes	No
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28) Are all of the Hemp/CBD products being sold where such products are considered legal under the governing State law?	Yes	No
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SECTION VI – ANY HEMP DERIVED THC (DELTA THC) OR ANY OTHER INTOXICATING CANNABINOID N/A

If hemp derived THC (Delta THC) or other intoxicating cannabinoid-containing products (e.g. Delta-8, Delta-9, Delta-10, THC-O, THC-V, THC-A, HHC, etc.), are sold by or on behalf of the Applicant, confirm the following questions:

- 29) All cannabinoid-containing products are extracted from legally cultivated hemp and manufactured solely in the US? Yes No
- 30) Does the Applicant attest that cannabinoid-containing products are hemp-derived and are NOT marijuana-derived? Yes No
- 31) Do all products contain **less than** 0.3% Delta-9 THC on a dry weight basis? Yes No
- 32) Has the Applicant ever had a favorable legal opinion regarding the sale of Hemp derived THC (Delta THC) products in the governing state? Yes No
- 33) Are products shipped or sold to states or venues with an unfavorable legal opinion regarding the sale of Hemp derived THC (Delta THC) products? Yes No
- 34) Do any Hemp derived THC (Delta THC) products contain caffeine?
If Yes, submit full labels and confirm the amount of caffeine per serving. Yes No
- 35) If products are tested and certified by a third-party laboratory, describe the testing and quality control procedures conducted to verify the safety and quality?
- 36) Do all packaging/labels and marketing materials include warnings for intoxicating effects and directions for use? Yes No

37) Is on-site consumption permitted on the Applicant's premise(s)? Yes No
If Yes, list the type of products being consumed below:

38) Will the Applicant or others on the Applicant's behalf, be serving Hemp Derived THC products, including at bars, restaurants, event venues or trade shows? Yes No

39) Will any Hemp derived THC beverages/foods be sold or distributed to any bars, restaurants or venues? Yes No

40) Is there any advertising or labeling for Hemp derived THC beverages suggesting they can be mixed with Alcohol? Yes No

41) Are all Hemp derived THC beverages/foods sold in single size serving containers/packages? Yes No
If No, explain:

42) Are all of the hemp derived THC (Delta THC) or other intoxicating cannabinoid-containing products being sold where such products are considered legal under the governing State law? Yes No

SECTION VII – VAPES PRODUCTS N/A

43) **Vape exposure** (including hemp/CBD/Delta vape products), provide the following information:

a. Name and address of manufacturer:

b. Is the Applicant aware of the PACT ACT for Vape Products? Yes No
Does the Applicant comply with the PACT ACT? Yes No

c. Provide the gross sales of each of the following types of vape products:

Vape Devices /Disposables	\$
Cartridges	\$
E-liquids	\$
Batteries	\$
Other:	\$

d. Are products UL8139 compliant? Yes No

e. Are E-liquids sold in childproof containers? Yes No

f. Do any products contain Marijuana, Nicotine or Tobacco? Yes No

g. Do battery chargers have auto safety cut-off to prevent overcharging? Yes No

h. Are there any replacement batteries? Yes No
If Yes, are they equipped with a protection circuit to prevent thermal runaway? Yes No

SECTION VIII – LABELING, MARKETING, AND ADVERTISING

44) Has legal counsel reviewed the labeling, advertising, and marketing materials and confirmed they are in compliance with the regulations established by the FDA and FTC? Yes No

45) Has the FDA or FTC ever contacted the Applicant about the labeling, advertising, and marketing materials? Yes No
If Yes, provide details and attach to the application.

46) Do all labels include a disclaimer that the FDA has not evaluated the claims on the labels and that the products are not intended to diagnose, treat, cure or prevent any disease? Yes No

47) Does the Applicant make any structure/function claims, or any disease claims for specific health conditions on the products on labels, websites or other marketing materials? Yes No
If Yes, provide specifics below and advise if documents substantiating each claim are maintained:

48) Does any of the packaging, marketing material, and any other literature appeal to children (e.g. packaging that looks like candy, juice boxes, cookies, toys, etc.)? Yes No
If Yes, provide packaging details on warnings designed to prevent access to minors in the general fill area at the end of the application.

SECTION VIII – QUALITY CONTROL AND REGULATORY COMPLIANCE

49) Product Withdrawal/Product recall:

- Is there a formal written product recall procedure? Yes No
If No, what is the anticipated date that a plan will be in place?
- Has there ever been a voluntarily or involuntarily recall or withdrawal, or is it anticipated that there will be a recall or withdrawal of any products for any reason? Yes No
If Yes, provide details:

50) Quality Assurance Program (QAP)/Quality Control Program (QCP):

- Is there a formal written Quality Assurance Program/Quality Control Program, including written Standard Operating Procedures that control operations? Yes No
- Provide name, title and contact information (email/phone) for Quality Assurance Program/Quality Control Program manager:

51) Are all facilities used to manufacture, process, pack, hold or store products registered with the FDA? Yes No

SECTION IX – REGULATORY EVENTS

52) In the past five (5) years, has the Applicant submitted a Serious Adverse Event Report (SAER) to the FDA or has the FDA notified the Applicant of an SAER submitted directly by a health care provider, firm or consumer? Yes No
If Yes, attach a comprehensive list of all Serious Adverse Events, along with copies of all reports and relevant documents.

53) Is there a SOP detailing how to identify and handle a SAER/SAE? Yes No

54) Has the Applicant been inspected by the FDA? Yes No

- Did the FDA issue a Form 483 or Warning Letter notifying the Applicant of any objectionable conditions? Yes No
If Yes, provide a copy and the Applicant's written response to the FDA.
- Has the FDA issued a closeout letter in response to any Form 483 or Warning Letters? Yes No

SECTION X – OPTIONAL COVERAGE ENHANCEMENTS

ITEM	DESCRIPTION	ANSWER	NOTE
HIRED & NON-OWNED AUTO			N/A
55) If the Applicant desires Hired & Non-Owned Auto Liability (HNOA) coverage, complete the below:			
a. Does the Applicant have a Commercial Auto Liability policy for the business?		Yes	No
b. Are there any autos registered to and owned by the Applicant for business use?		Yes	No
c. Will the Applicant have more than five employees using their personal auto for business use?		Yes	No
d. Will any vehicle be operated beyond a 50-mile radius of the business location address on a weekly basis?		Yes	No
e. Will any vehicle be used for product delivery?		Yes	No
(Note: If "Yes" was answered to any of the questions within 55) a.- e., HNOA coverage will be unavailable.)			
CYBER LIABILITY			N/A
56) If the Applicant desires Cyber Liability coverage, complete the below:			
a. Does the company configure firewalls to restrict inbound and outbound network traffic to prevent unauthorized access to internal networks?		Yes	No
b. Does the company update (e.g., patch, upgrade) commercial software for known security vulnerabilities per the manufacturer's advice?		Yes	No
57) Does the third-party technology service provider meet the regulatory provisions required by the Applicant's company (e.g., PCI-DSS, HIPAA, SOX, etc.)?			
a. Does the Applicant's website have a "payment cart"?		Yes	No
b. Does the Applicant collect medical information?		Yes	No
(Note: If the Applicant answered "No" to questions 57) a. and b., or has a payment cart that is not PCI-DSS compliant or collects medical information, Cyber Coverage will be unavailable.)			
HUMAN CLINICAL TRIALS			N/A
58) If the Applicant desires Human Clinical Trials coverage, include a copy of the Informed Consent & Protocol documents and complete the below.			
(Note: Coverage is only available for Phase 1 and Phase 2 Trials, including any research and development performed in conjunction with the planned research trial.)			
a. Are signed contracts utilized between the Applicant and any Principal Investigators or Trial Sponsors?		Yes	No
b. Are all Principal Investigators required to carry their own Products Coverage?		Yes	No
c. Are all subcontractors providing services in connection with the Applicant's trial required to carry their own Professional Liability Insurance Coverage?		Yes	No
d. Are all participants to sign an informed consent document?		Yes	No
e. Are all clinical trials approved and subject to oversight by an Institutional Review Board?		Yes	No
f. Are the Applicant's Principal Investigator and Institutional Review Board related to the Sponsor?		Yes	No
59) Describe the following details for the Applicant's Clinical Trial:			
a. Overall Trial Description:			
b. Name of the Trial:			
c. Products being tested:			
d. Number of participants:			
e. Trial Dates/Length of Trial:			
(Note: If the Applicant answered "No" to questions 58) a., b., and d., or "Yes" to question 58) f., Human Clinical Trials Coverage will be unavailable.)			

SECTION XI – LOSS HISTORY DETAILS

60) Have there been any insured or uninsured losses and/or claims in the past five (5) years? Yes No

61) Is the Applicant aware of any investigation, incident, condition, circumstance, lawsuit, legal action or suspected defect in any product or work, which has resulted in or may result in demand for damages or claims against the Applicant that are not listed in the five (5) years carrier loss history? Yes No
If Yes, attach a detailed explanation.

62) Has any insurer cancelled coverage with the Applicant in the past five (5) years? Yes No
If Yes, provide details including the reason why:

63) Current Carrier (check N/A if no current coverage) N/A

Is the current carrier offering renewal? Yes No

Coverage Form:	Occurrence	Claims-Made	If Claims-Made, Retroactive Date:
Limits:	\$	Deductible:	\$
Premium:	\$	Rate:	\$
64) Desired Limits:	\$	Desired Deductible:	\$

For detailed information on regulatory requirements and definitions, the Applicant may find useful references at: www.fda.gov and www.ftc.gov

Note: Coverage will not apply to products containing ingredients banned by the FDA or any governmental body or ruling agency including but not limited to Steroids. Including any product, supplement, additive, substance, ingredient or compound controlled or banned by any governmental body or ruling agency or additions/changes to the Anabolic Steroid Control Act of 1990 including amendments thereto or the Anabolic Steroid Control Act of 2005; DMAA (Dimethylamylamine) (1,3 – Dimethylamylamine); Ephedra; Ephedrine Alkaloids; or Fenfluramine (N-Nitroso-Fenfluramine); Kratom; or Phenibut.

General fill-in area for further explanation:

Fraud Notices

Applicable in AL, AR, DC, LA, MD, NM, RI and WV: Any person who knowingly (or willfully)* presents a false or fraudulent claim for payment of a loss or benefit or 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. *Applies in MD only.

Applicable in CO: 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 policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder 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.

Applicable in FL and OK: 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)*. * Applies in FL only.

Applicable in KS: 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 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.

Applicable in KY, NY, OH and PA: 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 to exceed five thousand dollars and the stated value of the claim for each such violation)*. *Applies in NY only.

Applicable in ME, TN, VA, and WA: 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 and denial of insurance benefits. *Applies in ME only.

Applicable in NJ: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

Applicable in OR: Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

Applicable in PR: Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

Applicable in all other States: 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 material fact, commits a fraudulent insurance act, which is a crime and may also be subject to civil penalty.

Other State Notices

Applicable in RI: THIS INSURANCE CONTRACT HAS BEEN PLACED WITH AN INSURER NOT LICENSED TO DO BUSINESS IN THE STATE OF RHODE ISLAND BUT APPROVED AS A SURPLUS LINES INSURER. THE INSURER IS NOT A MEMBER OF THE RHODE ISLAND INSURERS INSOLVENCY FUND. SHOULD THE INSURER BECOME INSOLVENT, THE PROTECTION AND BENEFITS OF THE RHODE ISLAND INSURERS INSOLVENCY FUND ARE NOT AVAILABLE.

I/We understand that this is an application for insurance only and that the completion and submission of this Application does not bind the Company to sell nor the applicant to purchase this insurance. I/We hereby declare that the above statements and particulars are true and I/we agree that this Application shall be the basis for any contract of insurance issued by the Company in response to it.

Electronic Signature of Applicant or Authorized Representative:

Title:

Date:

If you prefer not to return the questionnaire with an electronic signature, please print and sign.