Industrial Hemp-Derived Extract Processing Operation

Completing the Application for Manufacturer of an Industrial Hemp-Derived Extract Intended for Human Consumption and what to expect during the food safety inspection of your processing location
Completing the Application

VDACS Industrial Hemp Processor Registration

Before processing industrial hemp into a hemp-derived extract for human consumption, you must have obtained an Industrial Hemp Processor Registration from VDACS. Information on this can be found at the following link: http://www.vdacs.virginia.gov/plant-industry-services-hemp.shtml
Applicable Laws and Regulations

As a food producer, you are required to meet certain standards. The following regulations are applicable to your food business. You should familiarize yourself with these regulations to prepare for the inspection and to educate yourself on how to provide safe, wholesome food to your customers.

• **Virginia Food Law**
• **21 CFR 117 Current Good Manufacturing Practices**
• **21 CFR 101 Food Labeling**

*Please note that additional regulations may apply depending on the product you are manufacturing*
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**Date of Application:** Enter the date you completed the application

**Industrial Hemp Processor Registration Number:** Enter your processor number assigned to you by VDACS

**County in which business is located:** Enter the County or City in which your food processing business is located

**Business Name:** Enter the name of your business

**Owner Name:** Enter your full, legal name

**Phone:** Enter the phone number to best reach you

**Email Address:** Enter the email address where you would like us to reach you

**Processing Location Address:** Enter the physical address of your processing location

**Business Mailing Address:** Enter the address where you would like to receive mail correspondence. This may or may not be the same as your physical address.
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**Water Supply:** Mark whether incoming water supply is from a public source, like the city’s water works, or if there is a private water supply like a well.

**Sewage Disposal:** Mark whether waste water is disposed into a public system, like the city’s waste disposal, or if there is a private disposal system, like a septic tank.

**Pets in the home:** Mark whether or not you have pets that live inside your home. If you do have pets, you must enclose any area that will be used for preparing food, storing food and washing and storing equipment, packaging, or other non-food materials. (*Only required for in-home operations*)

**Number of employees, including owner:** Enter the number of employees for your business, including yourself.

**Hours of operation:** Enter the weekdays and times that operation would normally occur.
Checklist of Required Information: This section is intended to help you make sure that you have included everything that is required. Please do not submit your application until all of the required information has been obtained and is ready to submit with your application.
Requirements for Manufacturers of Industrial Hemp Extracts

Please thoroughly review the requirements listed in the application and be prepared with a plan to meet those requirements.
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Documentation of zoning/commercial kitchen approval to operate a food processing business on the property

Contact your county or city’s zoning office and inquire about whether you can have a food business on the property. If they will allow it, ask for written documentation confirming this. It can be in the form of letter, email, license or other.

Alternatively, if you are using a community or shared kitchen, provide written documentation from that facility that you have permission to use it for your manufacturing business.
Completing the Application

Diagram of food processing and storage areas

Provide a diagram of your processing facility that clearly indicates each area used for: storage of ingredients, packaging materials, finished products; manufacturing processes; warewashing, and handwashing; restrooms; and any other areas used in the facility for manufacturing your products.

*Special note for homes with pets: indicate **clearly** on the diagram how the pet is excluded from these areas. Indicate their route for getting in and out of your home that does not include passing through areas used for your food business.

*Special note for commercial kitchens: all materials used for your food business must be stored at the commercial kitchen.
Employee Training and Records

Provide documentation that employee training was completed. A template you may use to document employee training is provided.

Training must be completed prior to submitting the application. Adequate training will cover principles of food hygiene and food safety, as appropriate to your food processing operation and the duties of each employee.

*Special note for single-employee businesses: Even if the owner is the only employee, a training record still needs to be maintained.
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Preventing Contamination from Personal Belongings*

Provide a written explanation on how you will prevent contamination from items not used in the manufacturing of your foods that will be offered for sale to the public. During the hours that your home is used as a food manufacturing facility, all areas must have first been cleaned and sanitized and all personal belongings must be removed from the countertop, tables, etc. where food will be manufactured.

*Only applicable if operating in the home
Preventing Contamination from Personal Belongings*

An adequate plan will address the following:

• Cleaning procedures prior to business operations
• Disallowing eating/drinking, chewing gum, using tobacco, and personal food preparation during business operations
• Removal of personal belongings
• Designation of cabinet/drawer/refrigerator storage areas for business use
• Prohibits sharing of ingredients between business and personal use

*Only applicable if operating in the home
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Preventing Allergen Cross-Contact

Provide a written plan for preventing allergen cross-contact. You should conduct a food allergen ingredient analysis, which considers all eight major food allergens. If your analysis identifies food allergens that will (or may be) in your products, you must have controls in place that prevent allergen cross-contact that includes all the products you manufacture for sale.
Preventing Allergen Cross-Contact

Things to consider when developing a written allergen cross-contact plan:

*Special consideration in the home: When you operate in a space that is also used for personal use, you must also consider cross-contact from ingredients/foods that you store, prepare and consume for personal use.

*Special consideration in a commercial kitchen: When you operate in a shared space that is also used by other businesses/individuals, you must also consider cross-contact from ingredients/foods that are used by other businesses/individuals.
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Requirements of Subparts C & G and Exemptions

Do **not** complete this section if your business is any of the following:

- A **very small business** that has attested. A very small business is one that averages less than $1,000,000 in sales of human food per year for 3 years. Even if you are a small business, you must still attest to FDA using the Qualified Facility Attestation module: https://www.access.fda.gov/
- A home food processing operation
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Requirements of Subparts C & G and Exemptions (continued)

Do **not** complete this section if your business is any of the following:

- Devoted strictly to making **seafood products** under 21 CFR 123
- Devoted strictly to making **100% juice** under 21 CFR 120. You cannot claim exemption from Subparts C & G if you do not treat your juice with a 5-log reduction in pathogens
- Devoted strictly to making **dietary supplements** under 21 CFR 111
- Devoted strictly to making **alcoholic beverages**

If you are making any of the above, PLUS other products, then you are subject to Subparts C & G and therefore must submit documentation.
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Requirements of Subparts C & G and Exemptions (continued)

If your business does not fit into any of the categories on the previous two pages, then you are required to comply with and supply, with your application, written documentation that you are a Preventive Controls Qualified Individual and have both a written Food Safety Plan and a Supply-Chain Program.

Use the resources provided in the application to find more information on the requirements and guidance on building your programs.
Product Label

You **must** provide a complete and final label for **each** of your products. Labeling is mandatory for all packaged foods.

Review the instructions on page 13 of the application. The product labeling is important and will be scrutinized for accuracy by the reviewer of your application. The checklist used by the reviewer of your application is included on the next page. It is being provided for your convenience, so that you may submit correct labels and thus, expedite the review of your application.
Statement of Identity

- If two labels, on front of package
- Describes food
- Parallel to bottom of label
- Bold text, prominent

Net Contents

- If two labels, on front of package
- Located in lower third of label (bottom)
- Parallel to bottom of label
- Bold text
- Distinct item (empty space around statement)
- US Customary and Metric units
- If liquid, declared in fluid measure
- If liquid, preceded by “net”
- If solid, declared by weight
- If solid, preceded by “net wt”
- If eggs, declared by count

Ingredients

- Matches recipe
- Listed in order of heaviest to least heavy
- Sub-ingredients in parenthesis
- No fanciful words (fresh, artesian, local)
- Text > 1/16 inch
- If spice blend, cannot list “spices” as ingredient
- “and/or” only used for fat or oil
- If two labels, on same as name/place and NF panel

Allergen Labeling

- Declared in ingredient list and/or contains statement
- If contains statement:
  - Only use text “Contains:_,_,_”
  - Only use: tree nut (specific), fish (specific), crustacean shellfish, peanut, soy, wheat, egg, milk
- ALL allergens listed
- Directly after ingredient statement
- Same type size as ingredients

Name and Place of Business

- Full physical address
- If two labels, on same as ingredients and NF panel

Claims

- If nutrient content claim or health claim, NF panel present
- Nutrient content claim meets definition (Appendix A and B of FDA guide)
- Must be truthful, not misleading OR meet FDA definition
- If gluten free, meets definition
- If healthy, meets definition (see 101.65(d)(2))
- If non-GMO, truthful
- If All Natural, truthful
- Disease claim not allowed

Other

- No text, picture, symbol between ingredients, name/address, NF panel
- No spelling mistakes on required information
Full Spectrum Hemp Extract

Ingredients: Hemp Seed Oil, Fractionated Coconut Oil, Full Spectrum Hemp Extract.

Grassy Fields Hemp Company LLC
14740 Country Road
Somewhere, VA 24019

1 fl oz (30 ml)
Example Label

Full Spectrum Salute
Industrial Hemp Extract

Ingredients: Hemp Seed Oil, Fractionated Coconut Oil, Full Spectrum Hemp Extract

Full Spectrum Salute LLC
12121 E. Main Street
Richmond, VA 23181

All statements made on the website are considered labeling and must also be in compliance.

We ♥ this Full Spectrum Hemp Extract because it is a true gift from nature!

Find our products online at: fullspecsalute.com
Full Spectrum Salute

Industrial Hemp Extract

1 fl oz (30 ml)

We ♥ this Full Spectrum Hemp Extract because it is a true gift from nature!

Ingredients: Hemp Seed Oil, Fractionated Coconut Oil, Full Spectrum Hemp Extract

Full Spectrum Salute LLC
12121 E. Main Street
Richmond, VA 23181

Find our products online at: fullspecsalute.com
Example Label

Full Spectrum Salute

Industrial Hemp Extract

1 fl oz (30 ml)

Ingredients: Hemp Seed Oil, Fractionated Coconut Oil, Full Spectrum Hemp Extract

Full Spectrum Salute LLC ∙ 12121 E. Main Street ∙ Richmond, VA 23181
Find us online at fullspecsalute.com
Ingredients: Full Spectrum Hemp Extract, Hemp Seed Oil, Fractionated Coconut Oil.

We love this full spectrum hemp extract because it supports a healthy brain and digestive system.

Full Spectrum Salute LLC
12121 E. Main Street
Richmond, VA 23181

1 oz

Find our products online at: fullspecsalute.com

Use of this type of language will cause the product to be a Dietary Supplement, and a Supplement Facts is required.

Net contents does not include metric units and is not in fluid measure.

Ingredients are not listed in order of heaviest to least heavy according to the recipe.

Intervening material between ingredients and name and address of business.

Ingredients and name and address of business not to the right of principal display panel.
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Product List and Planned Distribution

In the left column, list the name of each of your products.

In the right column, list the outlets where you intend on selling your products to the consumer. Examples: customer pick-up from the facility, delivery to customer home or event, Farmers Market, grocery stores, convenience stores, restaurants, over the internet to be shipped via USPS, UPS, FedEx.
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Ingredient List and Source

In the left column, list the name of each ingredient you will use. In the right column, list the place you will purchase each ingredient. Where you obtain your ingredients is important—they must come from approved sources. All industrial hemp used for your products must be obtained from growers that are in compliance with the requirements of the state where grown.
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Product Information Sheet

**Business Name:** Enter the name of your Business

**Date:** Enter the date you submitted this recipe

**Product Name:** Enter the name of the product this process is for

**Trade Secret:** Mark this box if your product is trade secret/confidential. Please note that you still need to provide the required information. Marking the product as trade secret protects it from being released under public Freedom of Information Act requests.

**Ingredients:** List each ingredient that will be used in your process. List the quantity of each ingredient used in ounces or grams.

**Processing Procedures from raw ingredients to finished product:** List each step in the process of making your finished product.
Review of Your Application

Once submitted, your application will be reviewed. The reviewer will contact you to let you know that your application has been received. Expect that the review could take several weeks. The reviewer will contact you with their comments and list of items needed to complete the review. Once the reviewer has determined your application is complete, the inspector will be notified that you are ready for inspection. The inspector will contact you to schedule a time they can conduct the initial inspection of your facility.
Special Note for Dietary Supplements

A dietary supplement is a product intended for ingestion that contains an ingredient(s) intended to add further nutritional value to, or supplement, the diet. You might be making a dietary supplement if you are adding certain ingredients that don’t have a history of use in food, rather they have a history of healing or wellness properties. You might be making a dietary supplement based on labeling statements or directions for use. You might also be making a dietary supplement if your product is in a pill, capsule, dropper, powder, tablet or other similar form.

If you are making a dietary supplement, you are required to meet 21 CFR 111. Your application will not be reviewed until you have all the dietary supplement paperwork in order.
Preparing for the Inspection
Items Needed: Hair Restraints, Clean Clothing, Disposable Gloves

• Proper hair restraints are required to be worn while processing. These can include:
  • Ball Cap (all hair must be covered by the cap)
  • Hair Net (recommended)
  • Beard Guard

• Make sure that you wear clean clothing/aprons, etc. while processing.

• Use proper handwashing and barriers (e.g. disposable gloves, tongs, etc.) when you are handling finished, ready-to-eat food products to reduce the chance of contamination from your hands to your products.
Items Needed to Clean Hands

Handwash Sink – use this sink to wash your hands in water above 100°F with soap for 20 seconds. The sink must be provided with single-use towels or other.
Items Needed to Clean Hands

Handwashing Sink provided with:

1. Soap
2. Paper towels
3. Trash can
4. Hot (100°F minimum) and cold running water on demand
5. Hand wash sign

Note: Do not use cloth towels for drying your hands. They can hold moisture and germs. Hand drying towels must be single use and disposed of after each use.
Items Needed to Clean Hands

You will need to post a handwash sign at your handwash sink(s). This sign or poster must notify food employees to wash their hands and it should be clearly visible.

How to wash your hands:
1. Wet hands with hot running water
2. Apply soap
3. Rub hands for 20-30 seconds
4. Clean under fingernails and between fingers
5. Rinse hands thoroughly under running water
6. Dry hands

You can obtain a pre-made hand wash sign from a restaurant supply company. Your inspector may also have a sign that they can leave with you at the time of your inspection.
Items Needed to Clean Equipment

**Warewashing sink** – soiled utensils shall be washed, rinsed and sanitized before use. These steps are traditionally performed in a 3 compartment equipment sink. See the following slide for more information on how to wash, rinse and sanitize without a 3 compartment sink. Additionally, this sink shall be designated only for utensil/equipment cleaning.
Three compartment sink

- WASH
- RINSE
- SANITIZE
Perform the WASH and RINSE steps in one basin, then use the second basin to submerge dishes in sanitizing solution for the SANITIZE step.
Items Needed to Clean Equipment

Warewashing Sink provided with:

1. Detergent
2. Hot (110°F minimum) and cold running water on demand
3. Sanitizer (more information on next slide)
4. Sanitizer test strips
5. Sink stoppers
Items Needed to Clean Equipment: Sanitizer

You will need to purchase a chemical sanitizer. Two of the most commonly used chemical sanitizers are:

- **Chlorine (Bleach)** – This is the same type of bleach that you can buy at your local grocery or supermarket.
  - **PROS** – easy to find and inexpensive
  - **CONS** – strong odor and causes bleaching of clothes
  - **Tips**: look for unscented, not splash-less, not concentrated

- **Ammonia Based Sanitizer (Quaternary Ammonium Chloride “QUATS”)** – This is typically found at any restaurant supply company or online.
  - **PROS** – mild odor, available in tablet form for easy measuring
  - **CONS** – not as easily obtained as chlorine, slightly more expensive than chlorine
Items Needed to Clean Equipment: Sanitizer Test Strips

You will need to purchase sanitizer test strips.

• These strips are used to test the concentration of the sanitizer solution that you use after washing dishes.
  • Chlorine should be used in room temperature water at 50 ppm
  • Quat should be used as directed on container, but usually 200 ppm

• Sanitizer test strips are specific to the type of sanitizer that you choose. In other words, sanitizer test strips for chlorine will not work with the ammonia based “QUATS” sanitizer and vice versa.
Items Needed to Clean Equipment

You may also be able to use an automatic dishwasher to sanitize through a hot water sanitization process, instead of using chemical sanitization. However, the final sanitizing rinse of the dishwasher must reach a minimum of 165°F. You can use temperature sensitive tape (obtained at a restaurant supply company or online) to determine if the dishwasher can reach the appropriate temperature.

*Your inspector will discuss these options with you during your inspection and may offer assistance on the proper procedure to wash/rinse/sanitize/air dry your equipment and utensils.*
How To Clean Soiled Equipment

Use of sink only
• Wash in hot soapy water
• Rinse soap from surface in clean water
• Submerge equipment in chemical sanitizer for at least 60 seconds
• Air dry – Do not towel dry

Use of dishwasher
• Perform wash cycle
• Perform sanitize cycle. In order to sanitize, water must be 165°F or above.
  • Option if water is not 165°F or above: remove clean dishes and submerge in chemical sanitizer for at least 60 seconds
  • Air dry – Do not towel dry
Incoming Water Supply: Public or Private Sourced

If you are using water from a public municipal source, then you will not need any documentation on water analysis. However, if you are using private/well water, then you will need to have the water tested annually, indicating that your water is safe for consumption and safe to be used for cleaning equipment and utensils. Keep records of all documentation to show to the inspector upon request.
Storing Your Food Products and Equipment/Utensils

• All food products (packaged and unpackaged) must be stored at least 4-6 inches above the floor level.

• You may store food products and equipment/utensils in cabinets, on shelving, pallets, tables, etc. as long as they are clean and won’t dirty the food or equipment/utensil.

• Food products, supplies, equipment, and utensils must be stored in a manner that prevents them from being contaminated. This can be accomplished by storing these items covered, inverted, and by maintaining your processing facility in a condition that ensures insect/rodent entry points such as doors, windows, floors, walls, ceiling, and the roof are in proper working order/condition.

• If you use raw foods (eggs, meat, etc.) in your food products, store them in the refrigerator **BElOW** any other ready-to-eat food products. This will help prevent any potential leakage onto other items stored in the refrigerator.
Storing Your Food Products and Equipment/Utensils

All dry goods, refrigerated food products, equipment/utensils, packaging material, etc. that are used for your business must be stored separately from all other personal supplies.
Storing Chemicals

It is important to make sure that all chemicals are stored away from your food products, equipment, and utensils. Find an area to segregate your chemicals (to include your sanitizer, medicines, first aid supplies, etc.) so that you can prevent potential contamination.
Processing Area Lighting

The lighting in your processing space that is above and around your food processing areas and unpackaged food products **MUST** have protective shields such as plastic tubing with endcaps (for fluorescent ceiling lighting), another form of a cover, or the light bulbs must be shatterproof. This prevents glass from getting into your product if breakage were to happen.
All floors, walls, and ceilings in the food preparation area(s) must be: made of a material that is smooth, easily cleanable, and non-absorbent and free from open cracks, holes, exposed insulation, and flaking/peeling paint. This means no carpeting, no exposed, and no unsealed wood. Walls must be painted in a glossy paint or other smooth cleanable surface. Surfaces that cannot be easily cleaned and sanitized contribute to a dirty work area and could contaminate your product.
Developing a Lot Code System

Assigning lot codes to your finished products allows them to be traceable in case a recall is necessary. Without a lot coding system, you will have to recall all your product if it is known to have been contaminated or potentially harmful to the public. A Julian coding system is one effective way to code your products.

How To Read a Julian Date Code

The Julian Date represents the date of production

For example: 144181
The first 3 digits (144) refer to the day of production (May 24 is day number 144 of the year)
The next 2 digits (18) refer to the year (2018)
The last 1 or 2 digits indicate the batch of that product (the example shows batch number 1 of that specific product)

|   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| JAN | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
| FEB | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 |
| MARCH | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 | 70 | 71 | 72 | 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 89 | 90 |
| APRIL | 91 | 92 | 93 | 94 | 95 | 96 | 97 | 98 | 99 | 100 | 101 | 102 | 103 | 104 | 105 | 106 | 107 | 108 | 109 | 110 | 111 | 112 | 113 | 114 | 115 | 116 | 117 | 118 | 119 | 120 |
| MAY | 121 | 122 | 123 | 124 | 125 | 126 | 127 | 128 | 129 | 130 | 131 | 132 | 133 | 134 | 135 | 136 | 137 | 138 | 139 | 140 | 141 | 142 | 143 | 144 | 145 | 146 | 147 | 148 | 149 | 150 | 151 |
| JUNE | 152 | 153 | 154 | 155 | 156 | 157 | 158 | 159 | 160 | 161 | 162 | 163 | 164 | 165 | 166 | 167 | 168 | 169 | 170 | 171 | 172 | 173 | 174 | 175 | 176 | 177 | 178 | 179 | 180 | 181 |
| JULY | 182 | 183 | 184 | 185 | 186 | 187 | 188 | 189 | 190 | 191 | 192 | 193 | 194 | 195 | 196 | 197 | 198 | 199 | 200 | 201 | 202 | 203 | 204 | 205 | 206 | 207 | 208 | 209 | 210 | 211 | 212 |
| SEPT | 244 | 245 | 246 | 247 | 248 | 249 | 250 | 251 | 252 | 253 | 254 | 255 | 256 | 257 | 258 | 259 | 260 | 261 | 262 | 263 | 264 | 265 | 266 | 267 | 268 | 269 | 270 | 271 | 272 | 273 | 274 |
| OCT | 275 | 276 | 277 | 278 | 279 | 280 | 281 | 282 | 283 | 284 | 285 | 286 | 287 | 288 | 289 | 290 | 291 | 292 | 293 | 294 | 295 | 296 | 297 | 298 | 299 | 300 | 301 | 302 | 303 | 304 |
| NOV | 305 | 306 | 307 | 308 | 309 | 310 | 311 | 312 | 313 | 314 | 315 | 316 | 317 | 318 | 319 | 320 | 321 | 322 | 323 | 324 | 325 | 326 | 327 | 328 | 329 | 330 | 331 | 332 | 333 | 334 |
The Day of Your Processing Location Inspection

Once your application has been approved, it is forwarded to the inspector that works in the area where your business is located. The inspector will contact you to confirm a date and time that they can meet you for the inspection.

*Special note for future inspections: Routine inspections are unannounced and unscheduled. The inspector will visit for inspection during the hours of operation you provided in your application.

In most cases you will NOT be asked to make your products during the inspection process. If the inspector needs to watch you make a food product, then they will inform you of that PRIOR to meeting with you.
Things To Keep in Mind

• You were approved to make the products that were included in your original application **ONLY**.

• If you want to make new products, those recipes and labels MUST be submitted to VDACS **PRIOR** to making and offering them for public sale.

• If you move to a new home or decide to make food products at another location, then you need to contact VDACS so that an inspection can be conducted in the new location **PRIOR** to any food products being made in that new location. Also note that your food product labels will need to change so that they reflect the new address.
Questions? Call 804-786-3520 or email foodsafety@vdacs.virginia.gov