

1 17 NCAC 04C .2001 is adopted without notice pursuant to G.S. 150B-1(d)(4) as follows:

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3 **SECTION .2000 – MANUFACTURER CERTIFICATION AND DIRECTORY**
4 **OF VAPOR AND CONSUMABLE PRODUCTS**
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6 **17 NCAC 04C .2001 DEFINITIONS**

7 (a) Certifying Manufacturer – Any manufacturer of vapor products or consumable products, as those terms
8 are defined in G.S. 14-313(a), that submits an initial certification or annual certification renewal to the
9 Secretary as required in G.S. 143B-245.11.

10 (b) Directory – A public listing on the Department’s website, www.ncdor.gov, of certifying manufacturers
11 whose initial certification or annual certification renewal have been submitted and approved by the
12 Secretary.

13 (c) Initial Certification Fee – The initial certification fee of \$2,000 as set by G.S. 143B-245.11(b)(2). The
14 initial certification fee is per certifying manufacturer and is not based on the number of vapor products or
15 consumable products submitted by the certifying manufacturer to the Department.

16 (d) Product Offered for Sale – Each unique vapor product name, consumable product name, or brand name
17 along with the product code or stock-keeping unit (SKU) constitutes a separate product offered for sale in
18 this State.

19 (e) Annual Renewal Fee – The annual certification renewal fee \$500.00 as set by G.S. 143B-245.11(b)(2).
20 The annual renewal fee is per certifying manufacturer and is not based on the number of vapor products or
21 consumable products submitted by the certifying manufacturer to the Department.

22 (f) Vapor Product – As defined in G.S. 14-313(a)(5), shall apply to the manufacturer certification of vapor
23 products and consumable products and the directory of vapor products and consumable products. The
24 definition of vapor product found in G.S. 105-113.4(13a) shall not apply to the administration of the
25 manufacturer certification and directory.

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27 History Note: Authority G.S. 143B-245.16;
28 Eff. March 1, 2025.
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1 17 NCAC 04C .2002 is adopted without notice pursuant to G.S. 150B-1(d)(4) as follows:
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3 **17 NCAC 04C .2002 DIRECTORY**

4 (a) Pursuant to G.S. 143B-245.12, beginning May 1, 2025, and on the first of each month thereafter, the
5 Department shall post to its website, www.ncdor.gov, a directory of certifying manufacturers. The directory
6 shall include the certifying manufacturer's name, along with a listing of the certified and approved products,
7 to include vapor product names, consumable product names, brand names, type or category of products,
8 and flavor of products.

9 (b) Only those products appearing on the directory shall be products offered for sale in this State. All other
10 products not appearing on the directory are prohibited from retail sale in this State.

11 (c) The Department, within each monthly publication of the directory, shall separately list additions or
12 removals of certifying manufacturers or their vapor products or consumable products for that month.

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14 History Note: Authority G.S. 143B-245.12; 143B-245.16;
15 Eff. March 1, 2025.
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17 NCAC 04C .2003 is adopted without notice pursuant to G.S. 150B-1(d)(4) as follows:

17 NCAC 04C .2003 CERTIFICATION

(a) Initial Certification Application - Beginning March 1, 2025, each certifying manufacturer shall electronically submit to the Department an initial certification application. The certifying manufacturer shall also electronically submit to the Department the initial certification fee at the time a certifying manufacturer submits the initial certification application.

(1) Manufacturers of vapor products or consumable products, offered for sale in this State prior to March 1, 2025, shall submit the initial certification application and initial certification fee by April 15, 2025.

(2) Manufacturers of vapor products or consumable products, who intend to offer products for sale in this State after March 1, 2025, shall submit the initial certification application and initial certification fee prior to shipping any vapor products or consumable products to a retailer, distributor, or wholesaler in this State for the purpose of making retail sales.

(b) The initial certification application and initial certification fee shall be completed through the Department's website at the following link: www.ncdor.gov.

(c) The initial certification application shall include the following information:

(1) the manufacturer's legal business name or assumed name for sole proprietors, business mailing address, daytime telephone number, fax number, and email address;

(2) federal employer identification number (FEIN) or social security number for proprietorships;

(3) a contact person, including that person's legal name, telephone number, fax number, and e-mail address.

(4) a designation of whether the manufacturer is requesting an initial certification or updating information to a previously submitted application;

(5) the seven-digit Secretary of State identification number assigned by the North Carolina Secretary of State when the manufacturer registered its business entity to do business in the State.

(6) the name, address, telephone number, fax number, and email address of a registered agent as required in 17 NCAC 04C .2006;

(7) a manufacturer located outside of the United States shall list the importers of any of the manufacturer's products to be sold in this State, as well as the name, address, telephone number, fax number, and email address of the importers registered agent.

1 8) a list of each vapor product or consumable product that is sold in this State to include the brand
2 name, category (e.g., e-liquid, power unit, device, e-liquid cartridge, e-liquid pod, disposable),
3 product name, product code or stock-keeping unit (SKU), and flavor; and
4 (9) the Food and Drug Administration (FDA) tracking number and order date for each vapor
5 product and consumable product offered by the manufacturer, and shall upload a copy of:
6 (A) the marketing granted order issued by the FDA pursuant to 21 U.S.C. § 387j;
7 (B) the acceptance letter issued by the FDA pursuant to 21 U.S.C. § 387j for a Timely
8 Filed Premarket Tobacco Product Application; or
9 (C) a document issued by the FDA or by a court confirming that the premarket tobacco
10 product application has received a denial order that is not yet in effect and remains
11 stayed or rescinded by FDA or vacated by a court; and
12 (10) the total certification fee due and remitted.
13 (d) Failure to submit the required information for the initial certification application or the initial
14 certification fee will result in a denial of the application and exclusion from the vapor product and
15 consumable product directory, pursuant to G.S. 143B-245.12(b). If an initial certification application is
16 denied pursuant to a provision of G.S. 143B-245.12(b), the certifying manufacturer shall electronically
17 resubmit to the Department a new initial certification application and initial certification fee.
18 (e) Failure to submit the initial certification application or initial certification fee to the Department 15-
19 days prior to the first of each month, when the Department makes the vapor product and consumable product
20 directory available for public inspection on the Department's website, will result in a manufacturer's
21 products offered for sale to be prohibited from retail sale in this State, pursuant to G.S. 143B-245.13 until
22 the manufacturer becomes certified.

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24 History Note: Authority G.S. 143B-245.11; 143B-245.12; 143B-245.13; 143B-245.16;
25 Eff. March 1, 2025.
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17 NCAC 04C .2004 is adopted without notice pursuant to G.S. 150B-1(d)(4) as follows:

17 NCAC 04C .2004 ANNUAL CERTIFICATION RENEWAL

(a) Beginning January 1, and not later than March 1, of each subsequent year, certifying manufacturers shall electronically submit to the Department an annual renewal application. The certifying manufacturer shall also electronically submit to the Department the annual renewal fee at the time a certifying manufacturer submits the annual renewal application.

(b) The annual certification renewal application and annual renewal fee shall be completed through the Department's website at the following link: www.ncdor.gov.

(c) The annual certification renewal application shall include the following information:

(1) the manufacturer's legal business name or assumed name for sole proprietors, business mailing address, daytime telephone number, fax number, and email address;

(2) federal employer identification number (FEIN) or social security number for proprietorships;

(3) a contact person, including that person's legal name, telephone number, fax number, and e-mail address.

(4) a designation of whether the manufacturer is requesting a renewal certification or updating information to a previously submitted application;

(5) the seven-digit Secretary of State identification number assigned by the North Carolina Secretary of State when the manufacturer registered its business entity to do business in the State.

(6) the name, address, telephone number, fax number, and email address of the registered agent as required in 17 NCAC 04C .2006;

(7) a manufacturer located outside of the United States shall list the importers of any of the manufacturer's products to be sold in this State, as well as the name, address, telephone number, fax number, and email address of the importers registered agent.

(8) a list of each vapor product or consumable product that is sold in this State to include the brand name, category (e.g., e-liquid, power unit, device, e-liquid cartridge, e-liquid pod, disposable), product name, product code or stock-keeping unit (SKU), and flavor; and

(9) the Food and Drug Administration (FDA) tracking number and order date for each vapor product and consumable product offered by the manufacturer, and shall upload a copy of:

(A) the marketing granted order issued by the FDA pursuant to 21 U.S.C. § 387j;

(B) the acceptance letter issued by the FDA pursuant to 21 U.S.C. § 387j for a Timely Filed Premarket Tobacco Product Application; or

(C) a document issued by the FDA or by a court confirming that the premarket tobacco product application has received a denial order that is not yet in effect and remains stayed or rescinded by FDA or vacated by a court; and

(10) the total certification fee due and remitted.

(d) The certifying manufacturer shall submit the annual renewal application and annual renewal fee to the Department during the annual renewal period to be timely. Failure of a certifying manufacturer to renew its certification or remit the annual renewal fee with the Department shall result in the expiration of the manufacturer's certification and exclusion from the vapor product and consumable product directory, pursuant to G.S. 143B-245.12(b).

(e) If a certifying manufacturer's certification expires, the certifying manufacturer shall electronically submit to the Department a new initial certification application and initial certification fee as set out in 17 NCAC 04C .2003, to be recertified.

History Note: Authority G.S. 143B-245.11; 143B-245.12; 143B-245.13; 143B-245.16;
Eff. March 1, 2025.

17 NCAC 04C .2005 is adopted without notice pursuant to G.S. 150B-1(d)(4) as follows:

17 NCAC 04C .2005 MATERIAL CHANGES TO CERTIFICATION

(a) Pursuant to G.S. 143B-245.11(e), certifying manufacturers shall notify the Department of any material change to the certification. Certifying manufacturers shall electronically submit the changes to the Department through their original initial certification application. There is no fee to update a certification. Certifying manufacturers shall notify the Department not more than 30 days after any material change to the certification.

(b) Failure to notify the Department of a material change to a certification may result in removal of the certifying manufacturer or its vapor products or consumable products from the directory.

History Note: Authority G.S. 143B-245.11; 143B-245.12; 143B-245.16;
Eff. March 1, 2025.

17 NCAC 04C .2006 is adopted without notice pursuant to G.S. 150B-1(d)(4) as follows:

17 NCAC 04C .2006 REGISTERED AGENT

(a) Pursuant to G.S. 143B-245.14, a manufacturer shall appoint a registered agent in this State for service of process. This applies to a manufacturer that is a sole proprietor in this State, an out-of-state business not required to register with the North Carolina Secretary of State to do business in this State, or a manufacturer located outside of the United States.

(b) A manufacturer located outside of the United States shall require its importers of any of its vapor products or consumable products, to be sold in this State, to appoint a registered agent.

(c) Certifying manufacturers shall notify the Department of the name, address, telephone number, fax number, and email address of their registered agent through the electronic initial certification application and annual certification renewal.

History Note: Authority G.S. 143B-245.14; 143B-245.16;
Eff. March 1, 2025.