

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Department of Revenue

RULE CITATION: 17 NCAC 04C .2001

DEADLINE FOR RECEIPT: Thursday, January 23, 2025

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Applicable to whole ruleset: *I am aware that the tobacco industry is heavily regulated by federal law. Are these rules consistent with existing federal regulations?*

Regarding item (f), I see that the statute regarding these rules uses the vapor product definition in G.S. 14, as reflected in your rule. Can you provide any context for why the two definitions in statute and what the difference is?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

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**
5

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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REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Department of Revenue

RULE CITATION: 17 NCAC 04C .2003

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In reviewing this Rule, the staff recommends the following changes be made:

On line 15, is the intent for the fee to be paid through the website? If so, no change. If not, clarify.

On line 16: the website listed is currently the front page for the department of revenue. Do you intend to have something on the front page to lead to this payment and registration? If not, include a more specific weblink.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

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.
26

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AGENCY: Department of Revenue

RULE CITATION: 17 NCAC 04C .2004

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In reviewing this Rule, the staff recommends the following changes be made:

*On line 4, consider adding “certifying manufacturers **of vapor products**”. While this is included in the definition of the term from .2001, including the detail at the beginning of this rule makes it more readable.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher
Commission Counsel

Date submitted to agency: January 14, 2025

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

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

4 (10) the total certification fee due and remitted.

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

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

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

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In reviewing this Rule, the staff recommends the following changes be made:

What is a “material change to the certification”? This phrase appears on lines 4, 7, and 9.

I recognize the phrase “material change to the certification,” comes from statute. However, it is unclear precisely what this means. As I understand it, the “certification” is the document itself and not the underlying product. Does this mean a “change material to the certification.”?

Alternatively, consider defining a “material change” in this rule.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher
Commission Counsel
Date submitted to agency: January 14, 2025

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

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3 **17 NCAC 04C .2005 MATERIAL CHANGES TO CERTIFICATION**

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

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

11
12 History Note: Authority G.S. 143B-245.11; 143B-245.12; 143B-245.16;
13 Eff. March 1, 2025.
14