

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, you must submit an amendment to registration within 5 days of the change.

§ 1271.27 Will FDA assign me a registration number?

(a) FDA will assign each location a permanent registration number.

(b) FDA acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA.

§ 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

(a) A copy of the Form FDA 3356 filed by each establishment will be available for public inspection at the Office of Communication, Training, and Manufacturers Assistance (HFM-48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of a registration number or the location of a registered establishment will be provided. The following information submitted under the HCT/P requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all HCT/P's;
- (2) A list of all HCT/P's manufactured by each establishment;
- (3) A list of all HCT/P's discontinued; and
- (4) All data or information that has already become a matter of public record.

(b) You should direct your requests for information regarding HCT/P establishment registrations and HCT/P listings to the Office of Communication, Training and Manufacturers Assistance (HFM-48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

Dated: January 2, 2001.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF THE TREASURY**Bureau of Alcohol, Tobacco and Firearms****27 CFR Parts 17 and 18**

[T.D. ATF-436]

RIN 1512-AB99

Delegation of Authority for Parts 17 and 18

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: Authority delegation. This final rule places most ATF authorities contained in parts 17 and 18, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" and requires that persons file documents required by parts 17 and 18, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.13 is being published. Through this order, the Director has delegated most of the authorities in 27 CFR parts 17 and 18 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT:

Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226 (202-927-8210).

SUPPLEMENTARY INFORMATION:**Background**

Pursuant to Treasury Decision 120-01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities

to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, in this final rule, the Director of ATF is rescinding all authorities of the Director in parts 17 and 18 which were previously delegated to a specified ATF officer and placing all authorities of the Director with the "appropriate ATF officer." Along with this final rule, ATF is publishing ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in parts 17 and 18, in which certain of these authorities are then delegated down to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 17 and 18 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the event of a change in delegation or in the event of a restructuring. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition to the above, this final rule also eliminates all references in the regulations which identify the ATF officer with whom an ATF form is filed. Thus, in lieu of identifying the authorized officer in the regulations, the form itself will indicate the officer with whom it shall be filed. Similarly, this final rule also amends parts 17 and 18 to provide that documents other than ATF forms (such as letterhead applications, notices and reports) will be filed with the "appropriate ATF officer." The "appropriate ATF officer" is the Director's delegate and will be identified in the accompanying ATF Order (ATF Order 1130.13, Delegation Order—Delegation of the Director's

Authorities in part 17 and 18). These changes will facilitate the identification of the officer with whom forms and other required submissions are filed in the event that authority to receive such submissions, or the title of the officer, changes.

Consistent with the above, this final rule makes various technical amendments to subpart C—Administrative and Miscellaneous Provisions of 27 CFR parts 17 and 18. Specifically, new §§ 17.7 and 18.12 will be added to recognize the authority of the Director to delegate regulatory authorities in parts 17 and 18, respectively, and to identify ATF Order 1130.13 as the instrument reflecting such delegations. Also, §§ 17.2 and 18.16 are amended to provide that the instructions on an ATF form identify the ATF officer with whom it is filed.

ATF has made or will make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of

entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 17

Alcohol and alcoholic beverages, Authority delegations, Claims, Drugs, Excise taxes, Foods, Reporting and recordkeeping requirements, Spices and flavorings, Surety bonds.

27 CFR Part 18

Administrative practice and procedure, Authority delegations, Excise taxes, Exports, Labeling, Reporting and recordkeeping requirements, Security measures, Spices and flavorings, Surety bonds.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 17—DRAWBACK ON TAXPAID DISTILLED SPIRITS USED IN MANUFACTURING NONBEVERAGE PRODUCTS

Paragraph 1. The authority citation for part 17 continues to read as follows:

Authority: 26 U.S.C. 5010, 5131–5134, 5143, 5146, 5206, 5273, 6011, 6065, 6091, 6109, 6151, 6402, 6511, 7011, 7213, 7652, 7805, 5062, 5081, 5111–5113, 5121, 5122, 5142, 5143, 5173, 5206; 31 U.S.C. 9301, 9303, 9304, 9306.

§§ 17.2, 17.3, 17.122 and 17.134 [Amended]

Par. 2. In part 17 remove the word “Director” each place it appears and add, in substitution, the words “appropriate ATF officer” in the following places:

- (a) Section 17.2(a);
- (b) Section 17.3(a), introductory text, and (c);
- (c) Section 17.122; and

(d) Section 17.134.

Par. 3. In addition to the amendment made above, § 17.2 is amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 17.2 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or at the ATF web site (<http://www.atf.treas.gov/>).

Par. 4. The first sentence of paragraph (b) of § 17.3 is revised to read as follows:

§ 17.3 Alternate methods or procedures.

* * * * *

(b) *Application.* A letter of application to employ an alternate method or procedure must be submitted to the appropriate ATF officer. * * *

* * * * *

§§ 17.6, 17.55, 17.121, 17.161, 17.171, 17.182 and 17.183 [Amended]

Par. 5. Part 17 is further amended by adding the word “appropriate” before the words “ATF officer” each place it appears in the following places:

- (a) Section 17.6;
- (b) Section 17.55;
- (c) Section 17.121(d);
- (d) Section 17.161;
- (e) Section 17.171;
- (f) Section 17.182; and
- (g) Section 17.183(a).

Par. 6. A new § 17.7 is added in Subpart A—General Provisions to read as follows:

§ 17.7 Delegations of the Director.

The regulatory authorities of the Director contained in this part 17 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR parts 17 and 18. ATF delegation orders, such as ATF Order 1130.13, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, VA 22150–5190, or by accessing the ATF web site (<http://www.atf.treas.gov/>).

Par. 7. Section 17.11 is amended by removing the definitions of “Alcohol and Tobacco Laboratory”, “ATF Officer”, and “Regional director (compliance)”, and by adding a new definition of “Appropriate ATF officer” and revising the definition of “Director” to read as follows:

§ 17.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18.

* * * * *

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of Treasury, Washington, DC 20226.

* * * * *

§§ 17.54, 17.101, 17.107, 17.108, 17.111, 17.112, 17.113, 17.114, 17.125, 17.141, 17.143, 17.147, 17.166, 17.167, 17.168, 17.170 and 17.183 [Amended]

Par. 8. Part 17 is further amended by removing the words “regional director (compliance)” or “regional directors (compliance)” each place it appears and adding, in substitution, the words “appropriate ATF officer” or “appropriate ATF officers”, respectively, in the following places:

- (a) Section 17.54;
- (b) Section 17.101;
- (c) Section 17.107;
- (d) Section 17.108(c);
- (e) Section 17.111 (a) introductory text and (b);
- (f) Section 17.112;
- (g) Section 17.113;
- (h) Section 17.114;
- (i) Section 17.125(a);
- (j) Section 17.141;
- (k) Section 17.143;
- (l) Section 17.147(a);
- (m) Section 17.166(c);
- (n) Section 17.167(b);
- (o) Section 17.168(a);
- (p) Section 17.170; and
- (q) Section 17.183(b) and (c).

Par. 9. The first three sentences of § 17.92 are revised into two sentences to read as follows:

Sec. 17.92 Filing of refund claim.

Claim for refund of special tax must be filed on ATF Form 2635 (5620.8), Claim—Alcohol, Tobacco and Firearms Taxes. The claim must set forth in detail sufficient reasons and supporting facts of the exact basis of the claim. * * *

* * * * *

Par. 10. The last sentence of § 17.101 is amended to remove the words “Regional directors (compliance)” and add, in substitution, the words “Appropriate ATF officers”.

§§ 17.105, 17.144 and 17.145 [Amended]

Par. 11. Part 17 is further amended by removing the phrase “with the regional

director (compliance)” each place it appears in the following places.

- (a) Section 17.105(b);
- (b) Section 17.144; and
- (c) Section 17.145.

Par. 12. Paragraph (b) of § 17.121 is amended to remove the phrase “with the Alcohol and Tobacco Laboratory”.

Par. 13. Section 17.122 is amended by removing the phrase “to the Alcohol and Tobacco Laboratory” and adding, in substitution, the phrase “appropriate ATF officer”.

Par. 14. The third sentence of paragraph (b) of § 17.125 is revised to read as follows:

§ 17.125 Adoption of formulas and processes.

* * * * *

(b) *Adoption of manufacturer's own formulas from a different location.*

* * * A letterhead notice must be filed with the appropriate ATF officer and be accompanied by two photocopies of each formula to be adopted. * * *

* * * * *

§§ 17.126 and 17.136 [Amended]

Par. 15. Part 17 is further amended by removing the phrase “to the Alcohol and Tobacco Laboratory” each place it appears in the following places:

- (a) Section 17.126(a); and
- (b) Section 17.136.

Par. 16. Section 17.131 is amended by removing the phrase “by the Alcohol and Tobacco Laboratory” each place it appears.

Par. 17. The fifth sentence of paragraph (a) of § 17.142 is removed, and the first sentence of paragraph (a) of § 17.142 is revised to read as follows :

§ 17.142 Claims.

(a) *General.* The manufacturer must file claim for drawback with the appropriate ATF officer who has the authority to approve or disapprove claims. * * *

* * * * *

PART 18—PRODUCTION OF VOLATILE FRUIT FLAVOR CONCENTRATE

Par. 18. The authority citation for part 18 continues to read as follows:

Authority: 26 U.S.C. 5001, 5172, 5178, 5179, 5203, 5511, 5552, 6065, 7805; 44 U.S.C. 3504(h).

Par. 19. Section 18.11 is amended by removing the definitions of “ATF officer” and “Regional director (compliance)” and by adding the definition of “Appropriate ATF officer” and revising the definition of “Registry number” to read as follows:

§ 18.11 Meaning of Terms.

* * * * *

Appropriate ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18.

* * * * *

Registry number. The number assigned to a concentrate plant or a bonded wine cellar for an approved application as required by Parts 18 and 24, respectively.

* * * * *

Par. 20. A new § 18.12 is added in subpart C—Administrative and Miscellaneous Provisions to read as follows:

§ 18.12 Delegations of the Director.

The regulatory authorities of the Director contained in this part 18 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18. ATF delegation orders, such as ATF Order 1130.13, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, VA 22150–5190, or by accessing the ATF web site (<http://www.atf.treas.gov/>).

§§ 18.13, 18.16 and 18.52 [Amended]

Par. 21. Part 18 is further amended by removing the word “Director” each place it appears and adding, in substitution, the words “appropriate ATF officer” in the following places:

- (a) Section 18.13(a), introductory text;
- (b) Section 18.16(a); and
- (c) Section 18.52(b).

Par. 22. Paragraph (b) of § 18.13 is revised to read as follows:

§ 18.13 Alternate Methods or Procedures.

* * * * *

(b) *Application.* A proprietor who desires to employ an alternate method or procedure shall submit a written application to the appropriate ATF officer. The application will specifically describe the proposed alternate method or procedure and set forth the reasons therefor. Alternate methods or procedures may not be employed until the application has been approved by the appropriate ATF officer. Authorization for any alternate method or procedure may be withdrawn whenever in the judgment of the appropriate ATF officer the revenue is jeopardized or the effective

administration of this part is hindered by the continuation of the authorization.

* * * * *

§§ 18.14, 18.22, 18.24 and 18.27 [Amended]

Par. 23. Part 18 is further amended by removing the words “regional director (compliance)” each place it appears and adding, in substitution, the words “appropriate ATF officer” in the following places:

- (a) Section 18.14(a), introductory text and (b);
- (b) Section 18.22(b);
- (c) Section 18.24; and
- (d) Section 18.27(a).

§§ 18.15, 18.17, 18.19 and 18.61 [Amended]

Par. 24. Part 18 is further amended by adding the word “appropriate” before the phrase “ATF officers” or “ATF officer” each place it appears in the following places:

- (a) Section 18.15;
- (b) Section 18.17;
- (c) Section 18.19; and
- (d) Section 18.61(a) and (b).

Par. 25. Section 18.16 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 18.16 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150-5190, or at the ATF web site (<http://www.atf.treas.gov/>).

Par. 26. Section 18.21 is amended by removing the words “to the regional director (compliance)”.

Par. 27. Section 18.26 is amended by removing the words “with the regional director (compliance)”.

Par. 28. Section 18.65 is revised to read as follows:

Sec. 18.65 Annual report.

An annual report, on Form 1695(5520.2), of concentrate plant operations shall be prepared by each proprietor and forwarded in accordance with the instructions for the form. When a proprietor permanently discontinues the business of manufacturing concentrate, the proprietor shall submit the annual report in accordance with the instructions for the form.

Signed: July 13, 2000.

Bradley A. Buckles,
Director.

Approved: August 1, 2000.

John P. Simpson,
Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01-1162 Filed 1-18-01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 20, 21 and 22

[T.D. ATF-435]

RIN 1512-AC13

Delegation of Authority for Parts 20, 21 and 22

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places all ATF authorities contained in parts 20, 21 and 22, title 27 Code of Federal Regulations (CFR), with the “appropriate ATF officer” and requires that persons file documents required by such parts, with the “appropriate ATF officer” or in accordance with the instructions for the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word “region.” Concurrently with this Treasury Decision, ATF Order 1130.9 is being published. Through this order, the Director has delegated all of the authorities in 27 CFR parts 20, 21 and 22 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT:

Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (telephone 202-927-8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120-01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of *chapter 51* of the

Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in parts 20, 21 and 22 that were previously delegated and places those authorities with the “appropriate ATF officer.” All of the authorities of the Director that were not previously delegated are also placed with the “appropriate ATF officer.” Along with this final rule, ATF is publishing ATF Order 1130.9, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Parts 20, 21 and 22, Distilled Spirits Plants, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 20, 21 and 22 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends parts 20, 21 and 22 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the “appropriate ATF officer” identified in ATF Order 1130.9. These changes will facilitate the