5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading in the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm.1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Robert J. DeLuca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G214, Silver Spring, MD 20993–0002, email: Robert.DeLuca@fda.hhs.gov, 301–796–

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 5, 2010 (75 FR 17093), FDA published a proposed rule to amend certain neurological device and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. Interested persons were given until July 6, 2010, to comment on the proposed rule.

II. Request for Comments

Following publication of the April 5, 2010, proposed rule, FDA received requests to allow interested persons additional time to comment. The requests asserted that the 90-day time period was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. The agency has considered the requests and is reopening the comment period until September 7, 2010. The agency believes the additional comment period allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: July 22, 2010.

David Dorsey.

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–18405 Filed 7–27–10; 8:45 am] BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 646

[Docket No. ATF 22P; AG Order No. 3179–2010]

RIN 1140-AA31

Implementation of the USA PATRIOT Improvement and Reauthorization Act of 2005 Regarding Trafficking in Contraband Cigarettes or Smokeless Tobacco (2006R–1P)

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice is proposing to amend the regulations of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) to implement certain provisions of the USA PATRIOT Improvement and Reauthorization Act of 2005 (enacted March 9, 2006) relating to trafficking in contraband cigarettes or smokeless tobacco. The new law amends the Contraband Cigarette Trafficking Act by: reducing the threshold amount of cigarettes necessary to trigger jurisdiction under the CCTA from a quantity in excess of 60,000 to a quantity in excess of 10,000; extending the provisions of the CCTA to cover contraband smokeless tobacco; imposing reporting requirements on persons, except tribal governments, who engage in delivery sales of more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco in a single month;

requiring that cigarettes and smokeless tobacco seized and forfeited under the CCTA be either used in law enforcement operations or destroyed; and by authorizing state and local governments, and Federal tobacco permittees to bring civil causes of action against violators of the CCTA.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before October 26, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period. ADDRESSES: Send comments to any of the following addresses—

• James P. Ficaretta, Program Manager, Mailstop 6N–602, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue, NE., Washington, DC 20226; Attn: ATF 22P. Written comments must appear in a minimum 12-point size of type (.17 inches), include your mailing address, be signed, and may be of any length.

• 202-648-9741 (facsimile).

• http://www.regulations.gov. Federal eRulemaking portal; follow the instructions for submitting comments.

You may also view an electronic version of this proposed rule at the http://www.regulations.gov site.

Comments may also be submitted electronically to ATF to http:// www.regulations.gov by using the electronic comment form provided on that site. You may also view an electronic version of this proposed rule at the http://www.regulations.gov site. Comments submitted electronically must contain your name and mailing address. They must also reference this document docket number, as noted above, and be legible when printed on 81/2" x 11" paper. ATF will treat comments submitted electronically as originals and it will not acknowledge receipt of comments submitted electronically. Interested parties will not be able to submit comments electronically to ATF via http:// www.regulations.gov after the comment period closes.

See the Public Participation section at the end of the **SUPPLEMENTARY INFORMATION** section for instructions and requirements for submitting written comments, and for information on how to request a public hearing.

FOR FURTHER INFORMATION CONTACT:

James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice; 99 New York Avenue, NE., Washington, DC 20226, telephone (202) 648–7094.
SUPPLEMENTARY INFORMATION:

I. Background

In 1978, the Contraband Cigarette Trafficking Act (CCTA), 18 U.S.C. Chapter 114, was enacted to deter the interstate smuggling of cigarettes where the taxation on tobacco products varies between the States. The Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) was given primary jurisdiction to enforce and administer the CCTA. Contraband cigarettes were originally defined as any quantity of more than 60,000 cigarettes that bear no evidence of the payment of applicable state tax.

The legislative history of the CCTA and ATF's investigative efforts over the years have established that organized crime has been involved in the diversion of legal tobacco products into the illegal market. Moreover, several investigations by ATF and its law enforcement partners have established links to international terrorist groups, including Hezbollah and al Qaeda. Since the enactment of the CCTA, cigarette smuggling has grown in complexity. Not only are cigarettes smuggled between low-tax and high-tax States, they are smuggled through international borders. The counterfeiting of legitimate brands is also very prevalent. The trafficking of contraband cigarettes is a worldwide problem. Billions of dollars of tax revenue are lost by all levels of government throughout the world due to the smuggling of cigarettes. Much of the illicit profit gained by organized crime and terrorist groups is used in furtherance of their criminal enterprises.

The trafficking in counterfeit and contraband tobacco products also poses a serious health risk to our society. There are no standards of production in counterfeit product. This allows for such things as biological or chemical contamination of the product. Furthermore, contraband cigarettes are more likely to be sold to underage persons than legitimate product. Finally, the sale of counterfeit and contraband products poses a serious financial threat to legitimate manufacturers, wholesalers, and retailers.

II. USA PATRIOT Improvement and Reauthorization Act of 2005—Proposed Rule

Public Law 109–177 (120 Stat. 192), the USA PATRIOT Improvement and Reauthorization Act of 2005 ("the Act"), was enacted on March 9, 2006. Section 121 of the Act made several amendments to the CCTA, 18 U.S.C. 2341 *et seq.* The provisions of section 121 and the proposed implementing regulations (if applicable), are discussed in the following paragraphs.

Section 121(a)—Threshold Quantity for Treatment as Contraband Cigarettes

Prior to amendment, section 2342 of the CCTA made it unlawful for any person knowingly to ship, transport, receive, possess, sell, distribute, or purchase contraband cigarettes. Contraband cigarettes were defined as any quantity in excess of 60,000 cigarettes that bear no evidence of the payment of applicable state tax. Section 121(a) of the Act amended the CCTA by reducing the number of cigarettes that trigger application of the CCTA from a quantity in excess of 60,000 to a quantity in excess of 10,000 and which bear no evidence of the payment of applicable state or local tax, if the States or local governments require such indicia of tax payment.

Proposed amendments to the regulations to reflect the statutorily imposed reduction to the CCTA threshold are contained in 27 CFR 646.141, 646.143, 646.146, and 646.147. The Department is also proposing to amend § 646.143 by adding a definition for the term "cigarette." The proposed definition reflects the meaning of the term set forth in the CCTA as amended, i.e., to update the existing regulatory language to conform to the statutory change.

Section 121(b)—Contraband Smokeless Tobacco

Section 121(b) amended the CCTA by extending its provisions to include contraband smokeless tobacco and by defining the terms "smokeless tobacco" and "contraband smokeless tobacco." The term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral or nasal cavity or otherwise consumed without being combusted. The term "contraband smokeless tobacco" means a quantity in excess of 500 single-unit consumersized cans or packages of smokeless tobacco, or their equivalent, that are in the possession of any person other

1. A person holding a permit issued pursuant to chapter 52 of the Internal Revenue Code of 1986 as manufacturer of tobacco products or as an export warehouse proprietor, a person operating a customs bonded warehouse pursuant to section 311 or 555 of the Tariff Act of 1930 (19 U.S.C. 1311, 1555), or an agent of such person;

- 2. A common carrier transporting such smokeless tobacco under a proper bill of lading or freight bill which states the quantity, source, and designation of such smokeless tobacco;
- 3. A person who is licensed or otherwise authorized by the State where such smokeless tobacco is found to engage in the business of selling or distributing tobacco products, and has complied with the accounting, tax, and payment requirements relating to such license or authorization with respect to such smokeless tobacco; or
- 4. An officer, employee, or agent of the United States or a State, or any department, agency, or instrumentality of the United States or a State (including any political subdivision of a State), having possession of such smokeless tobacco in connection with the performance of official duties.

Proposed regulations that implement the provisions of section 121(b) are in 27 CFR 646.143, 646.146, 646.147, and 646.154.

Section 121(c)—Recordkeeping, Reporting, and Inspection

Section 121(c) of the Act amended the CCTA by:

- Authorizing the Attorney General to prescribe regulations concerning additional recordkeeping requirements that he considers appropriate for purposes of enforcement of the CCTA on persons who ship, sell, or distribute more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco in a single transaction.
- Requiring persons, except for tribal governments, who engage in a delivery sale, and who ship, sell, or distribute more than 10,000 cigarettes or 500 single-unit consumer-sized cans or packages of smokeless tobacco within a single month, to submit to the Attorney General a report that sets forth the following:
- 1. The person's beginning and ending inventory of cigarettes and cans or packages of smokeless tobacco (in total) for such month.
- 2. The total quantity of cigarettes and cans or packages of smokeless tobacco that the person received within such month from each other person (itemized by name and address).
- 3. The total quantity of cigarettes and cans or packages of smokeless tobacco that the person distributed within such month to each person (itemized by name and address) other than a retail purchaser.
- Adding the term "delivery sale," which means any sale of cigarettes or smokeless tobacco in interstate commerce to a consumer if—

(a) The consumer submits the order for such sale by means of a telephone or other method of voice transmission, the mails, or the Internet or other online service, or by any other means where the consumer is not in the same physical location as the seller when the purchase or offer of sale is made; or

(b) The cigarettes or smokeless tobacco are delivered by use of the mails, common carrier, private delivery service, or any other means where the consumer is not in the same physical location as the seller when the consumer obtains physical possession of the cigarettes or smokeless tobacco.

Proposed regulations that reflect the new CCTA requirements regarding contraband smokeless tobacco are in 27 CFR 646.143 and 646.146. The regulatory language is identical to the statutory language.

• Specifying that any report required to be submitted under the CCTA to the Attorney General must also be submitted to the Secretary of the Treasury and to the attorneys general and the tax administrators of the States from where the shipments, deliveries, or distributions both originated and concluded.

Proposed regulations that reflect the new CCTA requirements regarding contraband smokeless tobacco are in 27 CFR 646.146. The regulatory language is identical to the statutory language.

Section 121(d)—Disposal or Use of Forfeited Cigarettes and Smokeless Tobacco

Pursuant to section 121(d) of the Act, any contraband cigarettes or contraband smokeless tobacco involved in any violation of the CCTA will be subject to seizure and forfeiture and will be either (1) destroyed and not resold, or (2) used for undercover investigative operations for the detection and prosecution of crimes, and then destroyed and not resold.

Proposed regulations that implement this new CCTA provision are in 27 CFR 646.155. The regulatory language is identical to the statutory language.

Section 121(e)—Effect on State and Local Law

Section 121(e) of the Act amended the CCTA to make it clear that the CCTA is not intended to affect the concurrent jurisdiction of a state or local government to enact and enforce its own cigarette tax laws, to provide for the confiscation of cigarettes or smokeless tobacco and other property seized for violation of such laws, and to provide for penalties for the violation of such laws. This section also amended the CCTA to make it clear that the CCTA is

not intended to inhibit or otherwise affect any coordinated law enforcement effort by a number of state or local governments, through interstate compact or otherwise, to provide for the administration of state or local cigarette tax laws, to provide for the confiscation of cigarettes or smokeless tobacco and other property seized in violation of such laws, and to establish cooperative programs for the administration of such laws. This statutory change does not necessitate any amendments to these regulations.

Section 121(f)—Enforcement

Section 121(f) of the Act creates a new civil cause of action allowing state and local governments and federal tobacco permittees under the Internal Revenue Code to prevent or restrain CCTA violations in Federal district court. In addition, these entities could also seek civil penalties and monetary damages, and injunctive or equitable relief. This statutory change does not necessitate any amendments to these regulations.

Section 121(g)—Conforming and Clerical Amendments

Section 121(g) made several conforming and clerical amendments to the CCTA (e.g., a change in the title of chapter 114 and a change in the section headings of sections 2343 and 2345) that do not necessitate any regulatory changes. This statutory change does not necessitate any amendments to these regulations.

III. Miscellaneous Amendment of the Regulations

In general, the regulations at 27 CFR 646.150 provide that each distributor of cigarettes must retain the records required by §§ 646.146 and 646.147 for three years following the close of the year in which the records are made. The distributor must keep the required records on his business premises. ATF is considering extending the record retention requirement to five years. The amendment would harmonize the regulations with the applicable statute of limitations for CCTA violations, which is five years. ATF is soliciting comments on this issue.

How This Document Complies With the Federal Administrative Requirements for Rulemaking

A. Executive Order 12866

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review" section 1(b), The Principles of Regulation. The Department of Justice has determined that this proposed rule is a "significant

regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this proposed rule has been reviewed by the Office of Management and Budget. However, this proposed rule will not have an annual effect on the economy of \$100 million, and will not 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. Accordingly, this proposed rule is not an "economically significant" rulemaking as defined by Executive Order 12866. The proposed information requirements are contained in records that are kept in the normal course of business. Likewise, the reporting requirements contained in this proposed rule merely augment existing federal law as set forth in the Jenkins Act, 15 U.S.C. 375.

B. Executive Order 13132

This proposed rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, the Attorney General has determined that this proposed regulation does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

C. Executive Order 12988

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-forprofit enterprises, and small governmental jurisdictions. The Attorney General has reviewed this proposed regulation and, by approving it, certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The proposed requirements apply only to entities that sell the threshold quantities of cigarettes or smokeless tobacco in a single

transaction. In addition, the proposed information requirements are contained in the records that are kept in the normal course of business and the proposed reporting requirements merely augment existing federal law as set forth in the Jenkins Act, 15 U.S.C. 375.

ATF estimates that this proposed rule will have an impact on no more than 3,000 businesses with the majority of those being small businesses. ATF further estimates that the annual economic impact will be less than \$700,000 per year. ATF estimates for this proposed rule are as follows:

Mailing Costs (stamp and envelope): $\$.50 \times 3,000$ businesses \times 12 months =

\$180,000.

Labor Costs: One hour of labor (\$13.50/hr) for filling out ATF F 5200.XX, filing and mailing × 3,000 × 12 = \$486.000.

E. Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act of 1996 (5 U.S.C. 804). This proposed rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

F. Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

G. Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44) U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Bureau of Alcohol, Tobacco, Firearms, and Explosives, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Chief, Document Services Branch, Bureau of Alcohol, Tobacco, Firearms, and

Explosives, at the address previously specified. Comments are specifically requested concerning:

- Whether the proposed collections of information are necessary for the proper performance of the functions of the Bureau of Alcohol, Tobacco, Firearms, and Explosives, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the proposed collections of information (see below);
- How the quality, utility, and clarity of the information to be collected may be enhanced; and
- How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

The collections of information in this proposed regulation are in 27 CFR 646.146, 646.147, and 646.150. This information is required to implement the provisions of the USA PATRIOT Improvement and Reauthorization Act of 2005 regarding trafficking in contraband cigarettes or smokeless tobacco. The likely respondents are businesses.

Estimated total annual reporting and/or recordkeeping burden: 36,000 hours.

Estimated average burden hours per respondent and/or recordkeeper: 12 hours.

Estimated number of respondents and/or recordkeepers: 3,000.

Estimated annual frequency of responses: 12.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Public Participation

A. Comments Sought

ATF is requesting comments on the proposed regulations from all interested persons. ATF is also specifically requesting comments on the clarity of this proposed rule and how it may be made easier to understand. All comments must reference this document docket number (ATF 22P), be legible, and include your name and mailing address. ATF will treat all comments as originals and it will not acknowledge receipt of comments.

Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

B. Confidentiality

Comments, whether submitted electronically or in paper, will be made available for public viewing at ATF, and on the Internet as part of the President's eRulemaking initiative, and are subject to the Freedom of Information Act. Commenters who do not want their name or other personal identifying information posted on the Internet should submit their comment by mail or facsimile, along with a separate cover sheet that contains their personal identifying information. Both the cover sheet and comment must reference this docket number. Information contained in the cover sheet will not be posted on the Internet. Any personal identifying information that appears within the comment will be posted on the Internet and will not be redacted by ATF.

Any material that the commenter considers to be inappropriate for disclosure to the public should not be included in the comment. Any person submitting a comment shall specifically designate that portion (if any) of his comments that contains material that is confidential under law (e.g., trade secrets, processes, etc.). Any portion of a comment that is confidential under law shall be set forth on pages separate from the balance of the comment and shall be prominently marked "confidential" at the top of each page. Confidential information will be included in the rulemaking record but will not be disclosed to the public. Any comments containing material that is not confidential under law may be disclosed to the public. In any event, the name of the person submitting a comment is not exempt from disclosure.

C. Submitting Comments

Comments may be submitted in any of three ways:

- *Mail:* Send written comments to ATF at the address listed in the **ADDRESSES** section of this document. Written comments must appear in a minimum 12-point size of type (.17 inches), include your mailing address, be signed, and may be of any length.
- Facsimile: You may submit comments by facsimile transmission to 202–648–9741. Faxed comments must:
 - (1) Be legible;
 - (2) Be on 8½ " x 11" paper;
- (3) Contain a legible, written signature; and
- (4) Be no more than five pages long. ATF will not accept faxed comments that exceed five pages.
- Federal eRulemaking Portal: To submit comments to ATF via the Federal eRulemaking portal, visit http://www.regulations.gov and follow

the instructions for submitting comments.

D. Request for Hearing

Any interested person who desires an opportunity to comment orally at a public hearing should submit his or her request, in writing, to the Director of ATF within the 90-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing is necessary.

Disclosure

Copies of this proposed rule and the comments received will be available for public inspection by appointment during normal business hours at: ATF Reading Room, Room 1E–063, 99 New York Avenue, NE., Washington, DC 20226; telephone: (202) 648–7080.

Drafting Information

The author of this document is James P. Ficaretta; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives.

List of Subjects in 27 CFR Part 646

Administrative practice and procedure, Authority delegations, Cigars and cigarettes, Claims, Excise taxes, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Smokeless tobacco, Surety bonds, Tobacco.

Authority and Issuance

Accordingly, for the reasons discussed in the preamble, 27 CFR Part 646 is proposed to be amended as follows:

PART 646—CONTRABAND CIGARETTES AND SMOKELESS TOBACCO

1. The authority citation for 27 CFR part 646 continues to read as follows:

Authority: 18 U.S.C. 2341-2346.

2. Section 646.141 is revised to read as follows:

§ 646.141 Scope of part.

The regulations in this subpart relate to the distribution of cigarettes in excess of 10,000 and smokeless tobacco in excess of 500 single-unit consumersized cans or packages in a single transaction.

3. Section 646.143 is amended by revising the definitions for "Business premises," "Contraband cigarettes," "Disposition," "Distributor," and "Exempted person" and by adding definitions for the terms "Cigarette," "Contraband smokeless tobacco,"

"Delivery sale," "Interstate commerce," and "Smokeless tobacco" to read as follows:

§ 646.143 Meaning of terms.

* * * * * *

Business premises. When used with respect to a distributor, the property on which the cigarettes or smokeless tobacco are kept or stored. The business premises include the property where the records of a distributor are kept.

Cigarette. (a) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(b) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a) of this definition.

Contraband cigarettes. Any quantity

of cigarettes in excess of 10,000, if—

(a) The cigarettes bear no evidence of

- (a) The cigarettes bear no evidence of the payment of applicable state or local cigarette taxes in the State or locality where such cigarettes are found;
- (b) The State or local government in which the cigarettes are found requires a stamp, impression, or other indication to be placed on packages or other containers of cigarettes to evidence payment of cigarette taxes; and
- (c) The cigarettes are in the possession of any person other than an exempted person.

Contraband smokeless tobacco. Any quantity of smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, or their equivalent, that are in the possession of any person other than an exempted person.

Delivery sale. Any sale of cigarettes or smokeless tobacco in interstate commerce to a consumer if—

- (a) The consumer submits the order for such sale by means of a telephone or other method of voice transmission, the mails, or the Internet or other online service, or by any other means where the consumer is not in the same physical location as the seller when the purchase or offer of sale is made; or
- (b) The cigarettes or smokeless tobacco are delivered by use of the mails, common carrier, private delivery service, or any other means where the consumer is not in the same physical location as the seller when the consumer obtains physical possession of the cigarettes or smokeless tobacco.

Disposition. The movement of cigarettes or smokeless tobacco from a person's business premises, wherever

situated, by shipment or other means of distribution.

* * * * *

Distributor. Any person who distributes more than 10,000 cigarettes, or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, in a single transaction.

Exempted person. (a) With respect to cigarettes in excess of 10,000, any person who is—

- (1) Holding a permit issued pursuant to chapter 52 of the Internal Revenue Code of 1954 as a manufacturer of tobacco products or as an export warehouse proprietor;
- (2) Operating a customs bonded warehouse pursuant to section 311 or 555 of the Tariff Act of 1930 (19 U.S.C. 1311 or 1555);
- (3) An agent of a tobacco products manufacturer, an export warehouse proprietor, or an operator of a customs bonded warehouse:
- (4) A common or contract carrier transporting the cigarettes involved under a proper bill of lading or freight bill which states the quantity, source, and destination of the cigarettes;
- (5) Licensed or otherwise authorized by the State, in which he possesses cigarettes, to account for and pay cigarette taxes imposed by that State; and who has complied with the accounting and payment requirements relating to his license or authorization with respect to the cigarettes involved; or
- (6) An officer, employee, or agent of the United States, of an individual State, or of a political subdivision of a State and having possession of cigarettes in connection with the performance of official duties.
- (7) Operating within a foreign-trade zone established under 19 U.S.C., section 81b, when the cigarettes involved have been entered into the zone under zone-restricted status or, in respect to foreign cigarettes, have been admitted into the zone but have not been entered in the United States.
- (b) With respect to smokeless tobacco in excess of 500 single-unit consumersized cans or packages, any person who is—
- (1) Holding a permit issued pursuant to chapter 52 of the Internal Revenue Code of 1986 as manufacturer of tobacco products or as an export warehouse proprietor, a person operating a customs bonded warehouse pursuant to section 311 or 555 of the Tariff Act of 1930 (19 U.S.C. 1311, 1555), or an agent of such person;
- (2) A common or contract carrier transporting such smokeless tobacco under a proper bill of lading or freight

bill which states the quantity, source, and designation of such smokeless tobacco:

- (3) Licensed or otherwise authorized by the State where such smokeless tobacco is found to engage in the business of selling or distributing tobacco products; and who has complied with the accounting, tax, and payment requirements relating to such license or authorization with respect to such smokeless tobacco; or
- (4) An officer, employee, or agent of the United States, of an individual State, or of a political subdivision of a State and having possession of such smokeless tobacco in connection with the performance of official duties.

Interstate commerce. Commerce between a State and any place outside the State, or commerce between points in the same State but through any place outside the State.

* * * * *

Smokeless tobacco. Any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral or nasal cavity or otherwise consumed without being combusted.

4. The centered heading preceding section 646.146 is revised to read as "Records and Reports."

5. Sections 646.146 and 646.147 are revised to read as follows:

§ 646.146 General requirements.

- (a) Each distributor of cigarettes or smokeless tobacco shall keep copies of invoices, bills of lading, or other suitable commercial records equivalent thereto relating to each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages. Dividing a single agreement for the disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumersized cans or packages into the delivery of smaller components of 10,000 cigarettes or less or smokeless tobacco of not more than 500 single-unit consumer-sized cans or packages does not exempt the distributor from the recordkeeping requirements of this part. The distributor shall include the information prescribed in § 646.147 in his commercial records of disposition.
- (b)(1) Except for a tribal government, each distributor who engages in a delivery sale, and who ships, sells, or distributes cigarettes in excess of 10,000, or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages, or their equivalent, within a single month, shall prepare and submit to the Director ATF Form

5200.XX, in accordance with the instructions on the form. Form 5200.XX shall include the following information:

(i) The distributor's beginning and ending inventory of cigarettes and cans or packages of smokeless tobacco (in total) for such month.

(ii) The total quantity of cigarettes and cans or packages of smokeless tobacco that the distributor received within such month from each other distributor (itemized by name and address).

(iii) The total quantity of cigarettes and cans or packages of smokeless tobacco that was distributed within such month to each person (itemized by name and address) other than a retail purchaser.

(2) A copy of completed ATF Form 5200.XX shall also be submitted by each distributor described in paragraph (b)(1) of this section to the Secretary of the Treasury and to the attorneys general and the tax administrators of the States from where the shipments, deliveries, or distributions both originated and concluded.

§ 646.147 Required information.

- (a) Distributors who are exempted persons. Each distributor who is an exempted person as defined in § 646.143 shall show the following information in his commercial records.
- (1) For each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumersized cans or packages to an exempted person; or for each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages to a person who is not an exempted person and which is delivered by the distributor to the recipient's place of business, the distributor shall show on dated records—
- (i) The full name of the purchaser (or the recipient if there is no purchaser);
- (ii) The street address (including city and state) to which the cigarettes or smokeless tobacco are destined; and

(iii) The quantity of cigarettes or smokeless tobacco disposed of.

(2) For each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumersized cans or packages, other than the dispositions specified in paragraph (a)(1) of this section, the distributor shall show on dated records—

(i) The full name of the purchaser (if

- (ii) The name, address (including city and state), and signature of the person receiving the cigarettes or smokeless tobacco;
- (iii) The street address (including city and state) to which the cigarettes or smokeless tobacco are destined;

- (iv) The quantity of cigarettes or smokeless tobacco disposed of;
- (v) The driver's license number of the individual receiving the cigarettes or smokeless tobacco;
- (vi) The license number of the vehicle in which the cigarettes or smokeless tobacco are removed from the distributor's business premises;

(vii) A declaration by the individual receiving the cigarettes or smokeless tobacco of the specific purpose of receipt (such as personal use, resale, delivery to another person, etc.); and

(viii) A declaration by the person receiving the cigarettes or smokeless tobacco of the name and address of his principal when he is acting as an agent.

- (b) Distributors who are not exempted persons. Each distributor who is not an exempted person as defined in § 646.143 shall show on dated commercial records the information specified in paragraphs (a)(2)(i) through (viii) of this section for each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumer-sized cans or packages.
- 6. Section 646.150 is amended by revising paragraph (b)(2) to read as follows:

§ 646.150 Retention of records.

* * * * *

(b) * * *

(2) The tobacco products manufacturer will keep the required record for each disposition of more than 10,000 cigarettes or smokeless tobacco in excess of 500 single-unit consumersized cans or packages from the agent's premises for the full retention period specified in paragraph (a) of this section; and

§ 646.154 [Amended]

- 7. Section 646.154(a) is amended by adding "or contraband smokeless tobacco" after "contraband cigarettes".
- 8. Section 646.155 is revised to read as follows:

§ 646.155 Forfeitures.

- (a) Any contraband cigarettes or contraband smokeless tobacco involved in any violation of the provisions of 18 U.S.C. chapter 114 shall be subject to seizure and forfeiture. The provisions of 18 U.S.C. chapter 46 relating to civil forfeitures shall extend to any seizure or civil forfeiture under this section. Any cigarettes or smokeless tobacco so seized and forfeited shall be either—
- (1) Destroyed and not resold; or (2) Used for undercover investigative operations for the detection and prosecution of crimes, and then destroyed and not resold.

(b) Any vessel, vehicle, or aircraft used to transport, carry, convey, or conceal or possess any contraband cigarettes or contraband smokeless tobacco with respect to which there has been committed any violation of any provision of 18 U.S.C. chapter 114 or the regulations in this subpart shall be subject to seizure and forfeiture pursuant to 49 U.S.C. 80302–80303. The provisions of 18 U.S.C. chapter 46 relating to civil forfeitures shall extend to any seizure or civil forfeiture under this section.

Dated: July 22, 2010.

Eric H. Holder, Jr.,

Attorney General.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2010-0459; A-1-FRL-9182-6]

Approval and Promulgation of Air Quality Implementation Plans; Rhode Island; Determination of Attainment of the 1997 Ozone Standard for the Providence, RI Area

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to determine that the Providence (All of Rhode Island) moderate 1997 8-hour ozone nonattainment area continues to attain the 1997 8-hour National Ambient Air Quality Standard (NAAQS) for ozone. This determination is based upon complete, quality-assured, certified ambient air monitoring data that show the area has monitored attainment of the 1997 8-hour ozone NAAOS for the 2007-2009 monitoring period. Preliminary data available through June 15, 2010 also are consistent with continued attainment. In addition, in accordance with the Clean Air Act, EPA is proposing to determine, that this area has attained the 1997 ozone NAAQS as of June 15, 2010, its applicable attainment date. DATES: Written comments must be received on or before August 27, 2010. **ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R01-OAR-2010-0459 by one of the following methods:

- 1. http://www.regulations.gov: Follow the on-line instructions for submitting comments.
 - 2. E-mail: arnold.anne@epa.gov

3. Fax: (617) 918-0047.

4. Mail: "Docket Identification Number EPA-R01-OAR-2010-0459," Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05-2), Boston, MA 02109-3912.

5. Hand Delivery or Courier. Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R01-OAR-2010-0459. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through http:// www.regulations.gov, or e-mail, information that you consider to be CBI or otherwise protected. The http:// www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http:// www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose

disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in http:// www.regulations.gov or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA. EPA requests that if at all possible, you contact the person listed in the FOR **FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays. FOR FURTHER INFORMATION CONTACT: Richard P. Burkhart, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109-3912, telephone number (617) 918-1664, fax

Burkhart.Richard@epa.gov. SUPPLEMENTARY INFORMATION:

number (617) 918-0664, e-mail

Throughout this document whenever "we," "us," or "our" is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. What actions is EPA taking?

II. What is the effect of these actions?

III. What is the background for these actions?
IV. What is EPA's analysis of the relevant air quality data?

V. Proposed Actions

VI. Statutory and Executive Order Reviews

I. What actions is EPA taking?

EPA is proposing to determine that the Providence (All of Rhode Island) moderate 8-hour ozone nonattainment area continues to attain the 1997 8-hour NAAQS for ozone. This determination is based upon complete, quality-assured and certified ambient air monitoring data that show the area has monitored attainment of the 1997 ozone NAAQS for the 2007–2009 monitoring period. Preliminary data available through June 15, 2010 are also consistent with continued attainment. In addition. under section 181(b)(2)(A) of the Clean Air Act (CAA), EPA is proposing to determine that this area has attained the 1997 ozone NAAQS by its applicable attainment date (June 15, 2010).

II. What is the effect of these actions?

Under section 181(b)(2)(A) of the CAA and the provisions of EPA's ozone implementation rule (see 40 CFR Section 51.902(a)), EPA is proposing to determine that this area has attained the