

Friday, September 16, 2011, from 9 a.m. until 3 p.m. in room 8E-089. The tentative meeting agenda includes introductions, agreement on facilitator and rules of procedure, presentations from DOE consultants on the results of their revised analysis of alternative candidate standard levels, and identification of the issues to be addressed by the negotiations, and any outstanding data needs.

Public Participation: Members of the public are welcome to observe the business of the meetings and to make comments related to the issues being discussed at appropriate points, when called on by the moderator. The facilitator will make every effort to hear the views of all interested parties within limits required for the orderly conduct of business. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, e-mail erac@ee.doe.gov no later than 5 p.m., Thursday, September 8, 2011. Please include "MV Work Group 091511" in the subject line of the message. An early confirmation of attendance will help facilitate access to the building more quickly. In the e-mail, please provide your name, organization, citizenship and contact information. Space is limited.

Anyone attending the meeting will be required to present government-issued identification. Foreign nationals will be required, per DOE security protocol, to complete a questionnaire no later than one week prior to the meeting, Thursday, September 8, 2011.

Participation in the meeting is not a prerequisite for submission of written comments. ERAC invites written comments from all interested parties. If you would like to file a written statement with the committee, you may do so either by submitting a hard or electronic copy before or after the meeting. Electronic copy of written statements should be e-mailed to erac@ee.doe.gov.

Minutes: The minutes of the meeting will be available for public review at <http://www.erac.energy.gov>.

Issued in Washington, DC, on August 29, 2011.

LaTanya R. Butler,
Acting Deputy Committee Management Officer.

[FR Doc. 2011-22457 Filed 9-8-11; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-2011-N-0467]

RIN 0910-AG43

Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the regulation of non-face-to-face sale and distribution of tobacco products and the advertising, promotion, and marketing of tobacco products. FDA is taking this action as part of its implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA is requesting comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, e-mail, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients.

DATES: Submit either electronic or written comments by December 8, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0467 and/or RIN number 0910-AG43, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0467 and

Regulatory Information Number (RIN 0910-AG43) 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 of 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>, 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: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, beth.buckler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Tobacco Control Act, enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the authority to regulate tobacco products (Pub. L. 111-31, 123 Stat. 1776). Among other things, the Tobacco Control Act requires FDA to issue regulations, by October 1, 2011, regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer (*i.e.*, a non-face-to-face or remote sale) in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification (section 906(d)(4)(A)(i) of the FD&C Act (21 U.S.C. 387f(d)(4)(A)(i))). The Tobacco Control Act also requires FDA to issue regulations, by April 1, 2012, to address the promotion and marketing of tobacco products that are sold or distributed through a non-face-to-face exchange in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products (section 906(d)(4)(A)(ii)). Furthermore, section 906(d)(1) of the FD&C Act provides that the Secretary of Health and Human Services (the Secretary) may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and

promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health.

On March 31, 2010, following the enactment of the Tobacco Control Act, and before FDA could issue the regulations required by section 906(d)(4)(A) of the FD&C Act, the Prevent All Cigarette Trafficking (PACT) Act of 2009 (Pub. L. 111–154; 124 Stat. 1087) became law. Among other things, the PACT Act makes cigarettes and smokeless tobacco¹ nonmailable matter, with certain exceptions, and requires Internet and other remote sellers to comply with all State, local, Tribal, and other laws that apply generally to sales of cigarettes or smokeless tobacco that occur entirely within the State in which the cigarettes or smokeless tobacco products are delivered, including laws imposing restrictions on sales to minors (18 U.S.C. 1716E, 15 U.S.C. 376a(a)(3)). In addition, the PACT Act requires Internet and other remote sellers to: (1) Verify the age of their customers prior to the sale through the use of commercially-available databases to ensure, among other things, that the purchaser is at least the minimum age required by law at the place of delivery, and (2) use a method of delivery that requires verification of the age and identification of the person accepting delivery of the product to ensure that the person is at least the minimum age required by law at the place of delivery (15 U.S.C. 376a(b)(4)). The PACT Act also directs the Attorney General of the United States to create and distribute a list of delivery sellers of cigarettes or smokeless tobacco that are not in compliance with the PACT Act. This list will be provided to the attorney general and tax administrator of every State, common carriers and other persons that deliver small packages to consumers in interstate commerce, including the U.S. Postal Service, and any other person that can promote the effective enforcement of the PACT Act (15 U.S.C. 376a(e)(1)(A)). The U.S. Postal Service and the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives are responsible for implementing the provisions of the PACT Act.

FDA has determined that additional information is needed about the non-face-to-face sale and distribution of tobacco products prior to issuing the regulations required by section 906(d)(4)(A)(i) of the FD&C Act.

¹The PACT Act defines the terms “cigarettes” and “smokeless tobacco” differently than the FD&C Act (see 15 U.S.C. 375(a)(2) and (a)(12) of the PACT Act and section 900(3) and (18) of the FD&C Act).

Furthermore, because the enactment of the PACT Act affects the non-face-to-face sale and distribution of cigarettes and smokeless tobacco, FDA is seeking information about how non-face-to-face sale and distribution practices for cigarettes and smokeless tobacco have changed or will change in light of the PACT Act and its implementing regulations (75 FR 29662, May 27, 2010; 75 FR 35302, June 22, 2010). FDA also has determined that additional information is needed about the advertising, promotion, and marketing of tobacco products prior to issuing regulations under sections 906(d)(4)(A)(ii) and 906(d)(1) of the FD&C Act. Specifically, FDA is seeking information about the advertising, promotion, and marketing of tobacco products sold or distributed through a non-face-to-face exchange. In addition, given the rapid expansion of the Internet and mobile technologies, FDA is seeking information about the advertising of tobacco products via the Internet, e-mail, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients.

FDA believes that issuing an ANPRM is the best approach for ensuring that the Agency has the information it needs to issue effective regulations under that section. FDA intends to use the information submitted in response to this document to inform its regulation of the sale and distribution of tobacco products through a non-face-to-face exchange and the advertising, promotion, and marketing of tobacco products.

II. Request for Comments and Information

FDA is seeking data, research, information, and comments related to the following:

A. Non-Face-to-Face Sale and Distribution of Tobacco Products

1. Other than direct mail, catalog, and Internet sales, what types of non-face-to-face sales and distribution methods are used to sell or distribute tobacco products to consumers?

2. Do the non-face-to-face sales and distribution methods differ depending on the type of tobacco product being sold (e.g., cigarettes, smokeless tobacco, or other products “made or derived from tobacco” subject to the Tobacco Control Act)? If so, how?

3. What are the methods used by minors to acquire tobacco products through a non-face-to-face exchange?

a. Which of these methods are minors most successful in using to obtain tobacco products?

b. What are the best data sources (other than Federal Government surveys) for information about the extent and character of such purchases by minors?

4. Since the enactment of the PACT Act, have minors found alternative methods to purchase and/or acquire cigarettes or smokeless tobacco products by a means other than a face-to-face exchange? If so, what are they?

5. What are the current technologies, procedures, or other methods used to ensure that the purchaser of a tobacco product through a non-face-to-face exchange is an adult, including age and ID verification?

a. How effective are these methods at preventing minors' access to tobacco products through a non-face-to-face exchange?

b. If these methods are not effective, which other technologies, procedures, or methods would work more effectively to prevent minors' access to tobacco products through a non-face-to-face exchange?

c. Do these methods differ depending on the type of non-face-to-face exchange (e.g., Internet, direct mail, catalog, telephone, etc.)? If so, how?

d. Is requiring an adult (whether or not the person who placed an order) to sign for the delivery of tobacco products adequate to ensure that tobacco products purchased through a non-face-to-face exchange are not delivered to minors? Or, is it necessary to require that the products be delivered only to the person who ordered them? Are there other requirements that could be placed on the delivery of tobacco products to prevent their delivery to minors?

6. What payment methods are used for the sale of tobacco products through non-face-to-face exchanges? Do these payment methods differ depending on the type of tobacco product purchased? If so, how?

7. To what extent are tobacco products sold through a non-face-to-face exchange sold at substantially lower prices than the same types of tobacco products sold through a face-to-face exchange? Do the price differences vary depending on the type of tobacco product purchased? If so, how?

8. What means are used to deliver tobacco products sold to consumers through non-face-to-face exchanges?

a. Do these means of delivery differ depending on the type of non-face-to-face exchange (e.g., Internet, direct mail, catalog, etc.)? If so, how?

b. Do these means of delivery differ depending on the type of tobacco product sold? If so, how?

c. Do these means of delivery differ depending on the location of the seller and/or purchaser? If so, how?

9. What strategies, if any, are used by tobacco product manufacturers to ensure that their tobacco products are not sold or distributed to minors through non-face-to-face exchanges by parties other than the manufacturer?

a. Do tobacco product manufacturers verify the effectiveness of these strategies? If so, how?

b. Are there any data available to verify the effectiveness of these strategies? If so, what are they?

10. How can FDA most effectively partner with other Federal agencies and State, local, territorial, and Tribal governments to prevent the sale and distribution of tobacco products to minors through non-face-to-face exchanges?

B. Advertising, Promotion, and Marketing of Tobacco Products

11. What forms of advertising, promotion, and marketing are used to promote the sale of tobacco products through non-face-to-face exchanges?

a. What are the current trends in these forms of advertising, promotion, and marketing?

b. Which of these forms of advertising, promotion, and marketing are appealing to minors?

c. Are there themes or techniques used in these forms of advertising, promotion, and marketing that are appealing to minors?

12. How are the Internet, e-mail, direct mail, telephone, smartphones, and other communication technologies used to direct tobacco product advertising, marketing, and promotion messages to specific recipients?

a. What are the current trends in these forms of advertising, promotion, and marketing?

b. Which of these forms of advertising, promotion, and marketing are appealing to minors?

c. Are there themes or techniques used in these forms of advertising, promotion, and marketing that are appealing to minors?

d. To what extent are databases with individual tobacco user information used to direct tobacco product advertising, marketing, and promotion messages to specific recipients?

13. What technologies, procedures or other methods are currently used by the tobacco industry (including, but not limited to, manufacturers, importers, distributors, and retailers) to restrict or minimize a minor's exposure to the forms of advertising, promotion, and marketing of tobacco products described

in questions 11 and 12 of section II.B of this document?

a. How effective are these methods at restricting or minimizing such exposure?

b. If these methods are not effective, what other technologies, procedures, or methods would work more effectively to restrict or minimize the exposure of minors to such advertising, promotion, and marketing?

c. Would the technologies, procedures, or other methods described in question 13b prevent such tobacco product advertising, promotion, and marketing from reaching adult consumers? If so, what alternatives are available to minimize minors' exposure while still enabling tobacco product information to be communicated to adults?

d. To the extent that minors' exposure to tobacco product advertising, promotion, and marketing cannot be eliminated, what restrictions or requirements could be placed on such advertising, promotion, and marketing to minimize its appeal to or influence on minors who are exposed to it?

e. Would the technologies, procedures, or other methods described in question 13d of section II.B of this document prevent the communication of tobacco product information to adult consumers? If so, what alternatives are available to minimize minors' exposure while still enabling tobacco product information to be communicated to adults?

14. Given the rapid growth of social media (e.g., Facebook, Twitter, YouTube, etc.), how can minors' exposure to tobacco product advertising, promotion, and marketing through these types of media be restricted or minimized?

III. Submission of 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 viewed electronically at <http://www.regulations.gov> or by visiting the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Authority: The ANPRM is issued under section 906 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f) and under the authority of the Commissioner of Food and Drugs.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-23096 Filed 9-8-11; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

30 CFR Parts 1202 and 1206

[Docket No. ONRR-2011-0004]

RIN 1012-AA00

Workshops To Discuss Revisions to Federal and Indian Coal Valuation Regulations: Advance Notice of Proposed Rulemaking

AGENCY: Office of Natural Resources Revenue, Interior.

ACTION: Notice of Public Workshops.

SUMMARY: The Office of Natural Resources Revenue (ONRR) announces three public workshops to discuss specific issues regarding the existing royalty valuation regulations at 30 CFR parts 1202 and 1206 for coal produced from Federal and Indian leases.

DATES: The public workshop dates and cities are:

Workshop 1—October 12, 2011
(8:30 a.m.–12 p.m. mountain time) in Denver, Colorado.

Workshop 2—October 18, 2011
(8:30 a.m.–12 p.m., central time) in St. Louis, Missouri.

Workshop 3—October 20, 2011
(8:30 a.m.–12 p.m. mountain time) in Albuquerque, New Mexico.

ADDRESSES: The public workshop locations are:

Workshop 1—Office of Natural Resources Revenue, Denver Federal Center, 6th Avenue and Kipling Street, Building 85, Auditoriums A–D, Denver, Colorado 80226, telephone number (303) 231–3585.

Workshop 2—Marriott St. Louis Airport, 10700 Pear Tree Lane, St. Louis, Missouri 63134, telephone number (314) 423–9700.

Workshop 3—Bureau of Land Management, Albuquerque District Office, 435 Montano Road, NW., Albuquerque, New Mexico 87102, telephone number (505) 761–8700.

FOR FURTHER INFORMATION CONTACT: Hyla Hurst, Regulatory Specialist, Office of Natural Resources Revenue, P.O. Box 25165, MS 61013C, Denver, Colorado 80225, telephone (303) 231–3495, fax number (303) 233–2225, e-mail hyla.hurst@onrr.gov.

SUPPLEMENTARY INFORMATION: The comment period for the Advance Notice