

5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: [PSO@AHRQ.hhs.gov](mailto:PSO@AHRQ.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the QAI Sys, Inc., PSO number P0161, to voluntarily relinquish its status as a PSO. Accordingly, QAI Sys, Inc. was delisted effective at 12:00 Midnight ET (2400) on August 10, 2016. AHRQ notes that that QAI Sys, Inc. submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on July 28, 2016. In addition, QAI Sys, Inc., P0046, was previously listed as a PSO in 2009; AHRQ accepted its request for voluntary relinquishment in 2013.

More information on PSOs can be obtained through AHRQ’s PSO Web site at <http://www.pso.AHRQ.gov>.

**Sharon B. Arnold,**  
Deputy Director.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-2495]

#### Submission of Warning Plans for Cigars; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Submission of Warning Plans for Cigars.” The draft guidance, when finalized, will help those involved in the manufacture, distribution, and sale of cigars in the United States understand the new cigar warning plan requirements under FDA’s final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance reiterates the required health warning statements and the requirements for random display and distribution that should be provided in cigar warning plans, and, when finalized, will help persons determine who should submit a warning plan, when a plan must be submitted, and what information should be included when submitting a plan.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 29, 2016.

**ADDRESSES:** You may submit comments as follows:

##### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note

that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

##### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2016-D-2495 for “Submission of Warning Plans for Cigars.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Submission of Warning Plans for Cigars."

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority ("deeming") (section 901(b) of the FD&C Act (21 U.S.C. 387a)). On May 10, 2016, FDA issued that rule, extending FDA's

tobacco product authority to cigars, among other products (81 FR 28973). Among the requirements that now apply to cigars are health warning statements prescribed under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of public health." The regulation specifies the health warning statements to be displayed and also requires the submission of warning plans that provide for the random, equal display and random distribution of the statements on cigar packaging and advertising.

The draft guidance discusses the regulatory requirements to submit warning plans, who submits a warning plan, the scope of a warning plan, when to submit a warning plan, what information should be submitted in a warning plan, where to submit a warning plan, and what approval of a warning plan means.

##### *II. Significance of Draft Guidance*

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on cigar warning plans. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### *III. Paperwork Reduction Act of 1995*

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 1143 have been approved under OMB control number 0910-0768.

##### **IV. Electronic Access**

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: August 25, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2016-D-0545]

#### **Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance document is notifying blood establishments that collect Whole Blood and blood components, that FDA has determined Zika virus (ZIKV) to be a relevant transfusion-transmitted infection (RTTI) and provides FDA's assessment. The guidance also provides recommendations to reduce the risk of transmission of ZIKV by Whole Blood and blood components. The guidance applies to the collection of Whole Blood and blood components. The guidance does not apply to the collection of Source Plasma. The guidance supersedes the February 2016 document entitled, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry" (February 2016 guidance), and the March 2016 document entitled, "Questions and Answers Regarding 'Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry'" no later than 12 weeks after the date of the issuance of this guidance. Implementation of the guidance will be immediate for blood establishments that collect Whole Blood and blood components in States and territories with local transmission of ZIKV by mosquitos, and will be phased in over 4 to 12 weeks in other States and territories using a tiered, risk-based approach. Blood establishments should follow the recommendations in the February 2016 guidance until the recommendations in the guidance document have been fully implemented.

**DATES:** The Agency is soliciting public comment, but is implementing this guidance immediately because the