Staff, 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–2017–D–0121 for ''Compliance Policy for Required Warning Statements on Small-Packaged Cigars.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, Silver Spring, MD 20993–0002, 1–877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Compliance Policy for Required Warning Statements on Small-Packaged Cigars.''

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act granted FDA the 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 other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) of the FD&C Act). 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, which permits restrictions on the sale and distribution of tobacco products that are ''appropriate for the protection of the public health.'' The rule specifies the health warning statements that must be displayed on cigar packaging and where those statements must be placed, among other requirements.

The guidance discusses FDA's compliance policy for cigars with packaging too small or otherwise unable to accommodate the warning statements and specifications required under the regulation.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on its compliance policy for cigars in small packaging. 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This 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 0910–0768.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: September 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20426 Filed 9–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

National Advisory Council on Migrant Health

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a National Advisory Council on Migrant Health (NACMH/Council) meeting has been scheduled. This meeting will be open to the public. The agenda for the NACMH meeting can be obtained by contacting the Designated Federal Officer (DFO) or accessing the Council Web site: *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html.*

DATES: The meeting will be held on November 7, 2017, 8:30 a.m.to 5:00 p.m.

ET, and November 8, 2017, 8:30 a.m. to 5:00 p.m. ET.

ADDRESSES: The address for the meeting is Doubletree by Hilton Raleigh Brownstone-University, 1707 Hillsborough Street, Raleigh, NC 27605. Phone: (919) 828–0811.

FOR FURTHER INFORMATION CONTACT: All requests for information regarding the NACMH should be sent to Esther Paul, DFO, NACMH, HRSA, in one of three ways: (1) By mail to: Esther Paul, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, 16N38B, Rockville, Maryland 20857; (2) by phone: (301) 594–4300; or (3) by email: *epaul@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The NACMH is a non-discretionary advisory body mandated by the Public Health Service (PHS) Act, Title 42 U.S.C. 218, to advise, consult with, and make recommendations to the Secretary of HHS and the Administrator of HRSA regarding the organization, operation, selection, and funding of migrant health centers and other entities funded under section 330(g) of the PHS Act (42 U.S.C. 254b). The NACMH Charter requires that the Council meet at least twice per year to discuss services and issues related to the health of migrant and seasonal agricultural workers and their families and to formulate their recommendations to the HHS Secretary and HRSA Administrator.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from a federal official and experts on issues facing agricultural workers, including the status of agricultural worker health at the local and national levels. In addition, the Council will hold a public hearing where migratory and seasonal agricultural workers will testify regarding matters affecting them. This hearing is scheduled for Tuesday, November 7, 2017 from 1:30 p.m. to 5:00 p.m. at the Doubletree by Hilton Raleigh Brownstone-University. Agenda items are subject to change as priorities indicate.

Public Participation: Members of the public will not be able to provide oral comments during the meeting. Please provide any written questions or comments for the NACMH to the DFO by October 27, 2017, using the address, phone number, or email provided above. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the DFO at least 10 days prior to the meeting.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–20422 Filed 9–22–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2015–D–3638]

Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional Review Boards; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a guidance entitled ''Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional Review Boards.'' The guidance is intended for institutions and Institutional Review Boards (IRBs) that are responsible for the review and oversight of human subject research conducted or supported by the U.S. Department of Health and Human Services (HHS) or regulated by FDA. The purpose of the guidance is to assist institutions and IRBs in preparing and maintaining minutes of IRB meetings (also referred to in the guidance as minutes) that meet the regulatory requirements for minutes set forth in FDA and HHS regulations. The guidance also provides general recommendations on the type and amount of information to be included in the minutes. The guidance announced in this notice finalizes the draft guidance of the same title dated November 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on September 25, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2015–D–3638 for ''Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional Review Boards.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the office of Dockets Management Staff 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