

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2016 THROUGH JUNE 30, 2017—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P160003, FDA-2016-M-2652	Biotronik, Inc	PRO-Kinetic Energy Cobalt Chromium Coronary Stent System	2/14/2017
P150039, FDA-2017-M-1121	Tryton Medical, Inc	TRYTON Side Branch Stent	2/21/2017
P160014, FDA-2017-M-1122	CeloNova BioSciences, Inc	COBRA PzF™ NanoCoated Coronary Stent System	2/21/2017
P100044/S023, FDA-2017-M-1228	Intersect ENT	PROPEL® Contour Sinus Implant	2/23/2017
P140017/S005, FDA-2017-M-1227	Medtronic, Inc	Melody™ Transcatheter Pulmonary Valve, Ensemble™ Transcatheter Valve Delivery System and Ensemble™ II Transcatheter Valve Delivery System	2/24/2017
P160016, FDA-2017-M-1713	Siemens Healthcare Diagnostics, Inc.	VERSANT® HCV GENOTYPE 2.0 Assay (LiPA)	3/14/2017
P110033/S020, FDA-2017-M-1714	Allergan	Juvéderm Vollure™ XC	3/17/2017
P160025, FDA-2017-M-1845	Biotronik, Inc	Astron Pulsar and Pulsar-18 Stent Systems	3/23/2017
P160009, FDA-2017-M-1950	iCAD, Inc	PowerLook® Tomo Detection Software	3/24/2017
P160024, FDA-2017-M-2594	Bard Peripheral Vascular, Inc	LifeStream Balloon Expandable Vascular Covered Stent	4/24/2017
P160043, FDA-2017-M-2767	Medtronic, Inc	Resolute Onyx Zotarolimus- Eluting Coronary Stent System	4/28/2017
P160040, FDA-2017-M-2766	Invivoscribe Technologies, Inc	LeukoStrat® CDx FLT3 Mutation Assay	4/28/2017
P160046, FDA-2017-M-2768	Ventana Medical Systems, Inc	VENTANA PD-L1 (SP263) Assay	5/1/2017
H150003, FDA-2017-M-3103	Wilson-Cook Medical, Inc	Flourish™ Pediatric Esophageal Atresia Device	5/12/2017
P160044, FDA-2017-M-3200	Abbott Molecular, Inc	Abbott RealTime CMV	5/18/2017
P160041, FDA-2017-M-3430	Roche Molecular Systems, Inc	cobas® CMV	6/1/2017
P140031/S028, FDA-2017-M-3579	Edwards Lifesciences LLC	Edwards SAPIEN 3™ Transcatheter Heart Valve and Accessories	6/5/2017
P160035, FDA-2017-M-3580	Berlin Heart, Inc	EXCOR® Pediatric Ventricular Assist Device	6/6/2017
P160047, FDA-2017-M-3778	AEGEA Medical, Inc	AEGEA Vapor System™	6/14/2017
H160002, FDA-2017-M-3839	Pulsar Vascular, Inc	PulseRider® Aneurysm Neck Reconstruction Device ("PulseRider")	6/19/2017
P160045, FDA-2017-M-3928	Life Technologies Corp	Oncomine™ Dx Target Test	6/22/2017
P150046, FDA-2017-M-3982	SciBase AB	Nevisense	6/28/2017
P150048, FDA-2017-M-3990	Edwards Lifesciences, LLC	Edwards Pericardial Aortic Bioprosthesis and Edwards INSPIRIS RESILIA Aortic Valve	6/29/2017
P160038, FDA-2017-M-3983	Illumina, Inc	Praxis™ Extended RAS Panel	6/29/2017

II. Electronic Access

Persons with access to the Internet may obtain the documents at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>.

Dated: September 12, 2017.

Anna K. Abram,

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

[FR Doc. 2017-20391 Filed 9-22-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-0121]

Compliance Policy for Required Warning Statements on Small-Packaged Cigars; 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 guidance for industry entitled "Compliance Policy for Required Warning Statements on Small-Packaged Cigars." The guidance is intended to assist any person who manufactures, packages, sells, offers to

sell, distributes, or imports cigars in small packages with respect to the warning statement requirements in FDA's regulations deeming other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The guidance describes FDA's compliance policy for cigars in packaging that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning statements. The guidance explains that FDA does not intend to take enforcement action with respect to cigars that do not comply with the size and placement requirements in the regulation when the information and specifications required under the regulation appear on the carton or other outer container or wrapper that could accommodate the required warning statements, or on a tag otherwise firmly and permanently affixed to the cigar package.

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

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–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.

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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.