10–07 and 31–10–08, both dated November 25, 2009, of Chapter 31, Indicating/Recording Systems in RUAG Aerospace Services GmbH Dornier 228 Airplane Maintenance Manual, TM–AMM–228–00014–080184, Revision 3, October 30, 2012.

(2) If any chafed or damaged wires are found during any inspection required in paragraph (f)(1) of this AD, before further flight, repair the affected wire(s) and assure correct installation of the wiring in the flight deck overhead panels by reattaching or replacing the wire tie attachment holders and securing any loose wires to the wire tie attachment holders with plastic wire ties following subjects 31–10–07 and 31–10–08, both dated November 25, 2009, of Chapter 31, Indicating/Recording Systems in RUAG Aerospace Services GmbH Dornier 228 Airplane Maintenance Manual, TM–AMM–228–00014–080184, Revision 3, October 30, 2012.

(3) To comply with the actions of this AD, you may insert a copy of this AD or a copy of the required actions of this AD into the airworthiness limitations section of the FAA-approved maintenance program (e.g., maintenance manual). This action may be done by an owner/operator (pilot) holding at least a private pilot certificate and must be entered into the airplane records showing compliance with this AD in accordance with 14 CFR 43.9 (a)(1)(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.173 or 135.439.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; fax: (816) 329–4090; email: *karl.schletzbaum@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2013–0244, dated October 4, 2013, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2013–1056. For service information related to this AD, contact RUAG Aerospace Services GmbH, Dornier 228 Customer Support, P.O. Box 1253, 82231 Wessling, Germany; telephone: +49 (0) 8153–30 2220; fax: +49 (0) 8153–30 4258; email: *custsupport.dornier228@ruag.com;* Internet: *http://www.ruag.com/en/Aviation/Aviation_Home.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on February 25, 2014.

Steven W. Thompson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–04699 Filed 3–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 175

[Docket No. FAA–2014–0131]

Notice of Availability of Proposed Advisory Circular for Passenger Notification Hazardous Materials Regulations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability; request for comments.

SUMMARY: In April 2013, the FAA Administrator chartered an Aviation Rulemaking Committee to develop recommendations that would establish an acceptable and effective means for air carriers to notify passengers of hazardous materials regulations. In November 2013, that Aviation Rulemaking Committee published a report containing its recommendations, as well as a proposed Advisory Circular with one or more means for air carriers to comply with passenger notification regulations. The FAA invites public comment on the Aviation Rulemaking Committee's recommended guidance.

DATES: Comments must be received by April 3, 2014.

ADDRESSES: Send comments identified by docket number FAA–2014–0131 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov*, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Richard Bornhorst or Kenneth Miller, International and Domestic Standards Division, Office of Hazardous Materials Safety, Federal Aviation Administration, 470 L'Enfant Plaza SW., Washington, DC 20024; telephone (202) 385–4906, or (202) 385–4916.

SUPPLEMENTARY INFORMATION:

Background

In April 2013, the FAA Administrator chartered an Aviation Rulemaking Committee (ARC) to develop recommendations that would establish an acceptable and effective means for air carriers to notify passengers of hazardous materials regulations. The ARC's charter can be viewed online at: *http://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/PassengerNotificationofHazardousMaterialsRegulations.ARC.Cht.04302013.pdf.*

In November 2013, the ARC submitted a report containing its recommendations, as well as an Advisory Circular (AC) proposing one or more means for air carriers to comply with passenger notification requirements under Title 49, Code of Federal Regulations (49 CFR) part 175. The FAA invites public comment on the ARC's recommended guidance, which can be found in the docket.

Comments Invited

As noted in the ARC's report, the ARC was comprised of experts representing air carriers, pilots, flight attendants, the

travel industry, as well as the FAA and Pipeline and Hazardous Materials Safety Administration. The ARC now seeks input from the general public and is particularly interested in feedback from entities subject to passenger notification regulations prescribed by U.S. Hazardous Materials (49 CFR 175.25). We note that operators transporting passengers in commerce under 14 CFR parts 135 and 91 are subject to the noted 49 CFR regulation, and it is important that a final AC provide a clear, acceptable, and effective means for these operators to communicate hazardous materials regulations to their passengers.

The ARC will review all comments received and consider them in its final recommendation to the FAA.

Issued in Washington, DC, on February 26, 2014.

Christopher Glasow,

Director, Office of Hazardous Materials Safety.

[FR Doc. 2014–04739 Filed 3–3–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2013–N–0745]

Action Plan for the Collection, Analysis, and Availability of Demographic Subgroup Data in Applications for Approval of Food and Drug Administration-Regulated Medical Products; Notice of Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on the issues and challenges associated with the collection, analysis, and availability of demographic subgroup data in applications for approval of FDA-regulated human medical products.

DATES: The public hearing will be held on April 1, 2014, from 9 a.m. to 3 p.m. Submit electronic or written requests to make oral presentations at the hearing by March 21, 2014. Electronic or written comments will be accepted after the hearing until May 16, 2014.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public hearing participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the corresponding docket number for the public meeting as follows: ''Docket No. FDA–2013–N–0745, Action Plan for the Collection, Analysis, and Availability of Demographic Subgroup Data in Applications for Approval of FDA-Regulated Human Medical Products, Public Hearing.''

FOR FURTHER INFORMATION CONTACT: Brenda Evelyn, Office of the Commissioner, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2303, Silver Spring, MD 20993 240–402–4201, email: *FDASIA907@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), the U.S. Congress directed FDA to produce a report that addressed the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups, including sex, age, race, and ethnicity, is included in applications submitted to FDA. Specifically, Congress asked FDA to consider four key topic areas: (1) A description of existing tools to ensure submission of demographic information along with how information about differences in safety and effectiveness of medical products according to demographic subgroup is made available to health care providers, researchers, and patients; (2) an analysis of the extent to which demographic data subset analyses are presented in applications; (3) an analysis of demographic subgroup representation in clinical trials submitted to FDA in support of product applications; and (4) an analysis of the extent to which a summary of product safety and effectiveness data by demographic subgroup is made available to the public in product labeling or on FDA's Web site.

To comply with that request, in August 2013, FDA published a report ''Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products.'' [1] The report describes the Agency's evaluation of 72 applications approved during 2011 for new molecular entity drug products, original biologics, and class III devices (premarket approval).

Regarding collection of data, although there was variation by product area, the evaluation found FDA's statutory and regulatory requirements, guidances, policies, and procedures generally informed sponsors about including tabulations of the demographic data on clinical trial participants and demographic subset analyses in their medical product applications.

Similarly, tools (e.g., application review templates and FDA standard operating policies and procedures) guide regulatory review staff in the assessment of marketing applications to ensure that demographic data and subset analyses are included in the information FDA uses in its review and approval processes.

However, the extent to which demographic subset data were analyzed varied across medical product types (drugs, biologics, and devices). Applications for drugs and biologics uniformly addressed subset analyses by sex, race, and age—that is, the applications mentioned demographic subsets in some way. The report noted that FDA's new drug application regulations (21 CFR part 314; specifically § 314.50) call for demographic analysis in all applications in the integrated summaries of safety and effectiveness. Guidance and standard operating procedures for drugs and biologics also emphasize the importance of such analyses. There are no regulations requiring demographic analysis for device applications. Nonetheless, the majority of the device applications contained a subset analysis for age and sex, with a lower percentage of applications containing a subset analysis for race and ethnicity. Inclusion did not necessarily mean that the data on patient subgroups was sufficient for meaningful analysis or to detect relevant subgroup effects.

The report stated that all biologics, drugs, and the majority of the medical

[1] FDA, ''Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products,'' August 2012, available at *http://www.fda.gov/downloads/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm365544.pdf*.