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*.

device applications reviewed provided the composition of clinical study participants by age, race, and sex. Participants' sex was the most consistently reported in the medical product applications. For approved drugs and biologics, the extent to which patients were represented in clinical trials by age and sex tended to reflect the disease indication studied. For devices, patient participation by age and sex varied by product area. Whites represented a high percentage of clinical trial study participants for biologic, drug, and medical device applications, and in many cases, other racial subgroups were underrepresented.

FDA's internal policies, procedures, and regulations encourage demographic subgroup information be included in marketing applications. Moreover, following medical product approval, FDA communicates available information to the public both on the demographic profile of the study participants and on the demographic data subset analyses using a variety of mechanisms: Initially with product labeling and publicly posted clinical reviews, and later, once a product is on the market, with consumer updates, safety alerts, labeling changes, and other mechanisms, as needed.

As is required by section 907 of FDASIA, in response to the findings in the report, FDA is developing an action plan to address improving the completeness and quality of analyses of data on demographic subgroups in labeling, the inclusion of such data in labeling, and improving the public availability of information on demographic subgroups to patients, health care providers, and researchers.

II. Purpose and Scope of the Public Hearing

As part of FDA's process in the development of the required action plan, the Agency has decided to hold a public hearing to obtain information and viewpoints from key stakeholders and expert members of the public on the following questions:

A. Demographic Subgroup Representation in Clinical Trials

1. What approaches might be used to encourage enrollment of representative proportions of subgroup participants in clinical trials consistent with disease prevalence in the underlying population being studied?

2. What sources could be used to define disease prevalence among subgroups? Are there priority areas for study in terms of disease/condition, or in terms of demographic subgroup?

3. What are best practices and considerations for developing inclusion and exclusion criteria for clinical trials generally and for the early stages of research?

4. What approaches should FDA use to standardize the capture of race and ethnicity information, including for studies conducted outside the United States?

B. Analysis of Demographic Subgroup Data

1. What are the statistical challenges in analyzing clinical trial data to evaluate subgroup differences?

2. Given that it is not feasible to power most studies to detect subpopulation differences, what approaches should be used to analyze subgroups to explore clinically relevant information?

3. How might additional clinically relevant information about subgroups be obtained in the postmarket setting?

C. Communication of Demographic Subgroup Information to the Public

1. What information regarding demographic subgroups is helpful to health care professionals to make informed decisions about the use of medical products? To consumers/patients? To researchers?

2. What is the best way for FDA to communicate and make accessible such information to health care professionals? To consumers/patients? To researchers?

III. Attendance and Registration

If you wish to attend the hearing or make an oral presentation during the hearing, you must register by submitting either an electronic request (see the Web address listed at the end of this paragraph) or written request (see **FOR FURTHER INFORMATION CONTACT**) by close of business on March 21, 2014. You must provide your name, title, business affiliation (if applicable), address, email address, and type of organization you represent (e.g., industry, consumer organization), and a brief summary of your presentation, if applicable (including the discussion topic(s) that will be addressed), to *http://www.eventbrite.com/e/fda-public-hearing-fdasia-section-907-tickets-10678512719* by March 21, 2014.

FDA will notify registered presenters of their scheduled presentation times. Persons registered to make an oral presentation should check in before the hearing and are encouraged to arrive early to ensure the designated order of presentation times. We will try to accommodate all persons who wish to present; however, the duration of each speaker's testimony may be limited by time constraints. Questions about the meeting may also be also submitted to *FDASIA907@fda.hhs.gov* prior to the April 1, 2014, meeting date.

The hearing is free and seating will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the numbers of participants from individual organizations as well as total number of attendees based on space limitations.

Registrants will receive confirmation once they have been accepted to attend the hearing. For those who cannot attend in person, information regarding viewing a live Web cast of the public hearing will be located on FDA's Web site.

If you need special accommodations due to a disability, contact Brenda Evelyn at 240–402–4021.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04625 Filed 3–3–14; 8:45 am]

BILLING CODE 4160–01–P