DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0035]

Considerations Regarding Food and Drug Administration Review and Regulation of Drugs for the Treatment of Amyotrophic Lateral Sclerosis; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing to obtain input on the Agency's regulation of drugs for the treatment and/or management of amyotrophic lateral sclerosis (ALS). FDA is holding this public hearing to allow patients, caregivers, advocates, health care providers, academia, industry, and other interested persons to give their perspectives on various aspects of the development of drugs for the treatment or management of ALS. The input from this public hearing will help inform the work of FDA offices that review applications for drugs for the treatment of ALS.

DATES: *Public Hearing:* The public hearing will be held on February 25, 2013, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or end early.

Presentations and Comments: Submit either electronic or written requests for oral presentations to David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**) by February 8, 2013. Submit electronic comments to *http://www.regulations.gov* by March 25, 2013. Submit written comments to the Division of Dockets Management (see **ADDRESSES**) by March 25, 2013. Either electronic or written comments will be accepted after the hearing until March 25, 2013.

ADDRESSES: The public hearing will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503B, Silver Spring, MD 20993–0002. Additional information on parking and public transportation may be accessed at *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Comments and Transcripts: Submit either electronic or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 45 days after the hearing.

FOR FURTHER INFORMATION CONTACT: David Banks, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5365, Silver Spring, MD 20993–0002, 301–796–8459, Email: *david.banks@fda.hhs.gov*, or Steve Morin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, Rm. 5343, Silver Spring, MD 20993–0002, 301–796–0161, Email: *steve.morin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

ALS, sometimes called Lou Gehrig's disease, is a rapidly progressive, invariably fatal neurological disease that attacks the nerve cells (neurons) responsible for controlling voluntary muscles. Messages from motor neurons in the brain (called ''upper motor neurons'') are transmitted to motor neurons in the spinal cord (called ''lower motor neurons'') and from them to particular muscles. In ALS, both the upper motor neurons and the lower motor neurons degenerate or die, ceasing to send messages to muscles. Unable to function, the muscles gradually weaken, waste away (atrophy), and twitch (fasciculations). Eventually, the ability of the brain to start and control voluntary movement is lost.

ALS causes weakness with a wide range of disabilities. Eventually, all muscles under voluntary control are affected, and patients lose their strength and the ability to move their arms, legs, and body. When muscles in the diaphragm and chest wall fail, patients lose the ability to breathe without ventilatory support. Most people with ALS die from respiratory failure, usually within 3 to 5 years from the onset of symptoms. However, about 10 percent of ALS patients survive for 10 or more years.

As many as 20,000 people in the United States have ALS, and an estimated 5,000 people in the United States are diagnosed with the disease each year. People of all races and ethnic backgrounds are affected. ALS most commonly strikes people between 40 and 60 years of age, but younger and older people also can develop the disease.

In 90 to 95 percent of all ALS cases, the disease occurs apparently at random with no clearly associated risk factors. Patients do not have a family history of the disease, and their family members are not considered to be at increased risk for developing ALS.

No cure has yet been found for ALS. However, several years ago FDA approved the first drug treatment for the disease, RILUTEK (riluzole). Clinical trials with ALS patients showed that RILUTEK prolongs survival by several months. Patients taking RILUTEK must be monitored for liver damage and other possible side effects. However, this first disease-specific therapy offers hope that new medications or combinations of drugs may one day slow the progression of ALS.

Profound unmet medical needs remain for patients with ALS. Patients need new treatments to provide symptomatic relief, and to slow, halt, reverse, or prevent ALS. In addition to fulfilling responsibilities to regulate clinical testing and marketing of new treatments for ALS, FDA facilitates the work of researchers and medical product manufacturers by providing expert technical assistance.

The purpose of this meeting is for FDA to hear from stakeholders regarding the needs and preferences of patients, as well as suggestions regarding how best to be responsive to those needs and preferences.

II. Purpose and Scope of the Hearing

FDA is holding this hearing to seek input from ALS patients, caregivers, advocates, academia, health care providers, the pharmaceutical industry, and other interested parties on their experience with, concerns about, and suggestions for, the way FDA regulates the scientific evaluation of, marketing authorization for, and postmarketing surveillance of, drugs for treatment of ALS. The scope of the presentations may include, but are not limited to, nonclinical testing, clinical trials, and decisions regarding marketing authorization and postmarketing surveillance of products for the diagnosis or treatment of this disease.

III. Attendance and/or Participation in the Public Hearing

The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register. Given the debilitating effects of ALS, FDA will employ all available measures to enable participation of people who are mobility-limited.

If you wish to make an oral presentation during the hearing, you must register by submitting a written or electronic request by close of business on February 8, 2013, to David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**). You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., industry, consumer organization). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**). We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see **ADDRESSES**). We will mail, email, or fax the schedule to each participant before the hearing. Participants are encouraged to arrive early to ensure the designated order of presentation.

If you need special accommodations due to a disability, please contact David Banks or Steve Morin (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days in advance.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner, and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)).

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Interested persons may submit either electronic comments for consideration to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific topics to which they refer. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

The hearing will be transcribed as stipulated in § 15.30(b). Transcripts of the hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.regulations.gov* approximately 45 days after the hearing. A transcript will also be available in either hard copy or on a 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: January 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02088 Filed 1–30–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1205]

Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of January 7, 2013 (78 FR 951). The document announced a public workshop entitled ''Accessible Standardized Medical Device Labeling.'' The document was published with the incorrect date for submission of presentation materials. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Mary Weick-Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5426, 301–796–6089, FAX: 301–847–8510, email: *Mary.Brady@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of January 7, 2013, in FR Doc. 951–953, on page 952, the following correction is made:

Under *Requests for Oral Presentations,* on page 952, in the first column, the sentences that read ''All requests to make oral presentations must be received by the close of registration on April 5, 2013, at 5 p.m. If selected for presentation, any presentation materials must be emailed to Mary Weick-Brady (see **FOR FURTHER INFORMATION CONTACT**) no later than March 29, 2013'' is changed to read ''All requests to make oral presentations must be received by the close of registration on April 5, 2013, at 5 p.m. If selected for presentation, any presentation materials must be emailed to Mary Weick-Brady (see **FOR FURTHER INFORMATION CONTACT**) no later than April 19, 2013.''

Dated: January 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02084 Filed 1–30–13; 8:45 am]

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