Approval (PMA) Applications for Low Glucose Suspend (LGS) Device Systems,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1748 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 are currently approved under OMB control number 0910–0485, the collections of information in 21 CFR part 812 are currently approved under OMB control number 0910–0078, and the collections of information in 21 CFR part 814 are currently approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 16, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–15541 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0469]

Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering To Optimize Medical Device Design; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design.'' The recommendations in this guidance are intended to improve the safety and effectiveness of devices and reduce use error. This draft guidance is not final; nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by September 19, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Molly Story, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2533, Silver Spring, MD 20993–0002, 301–796–1456, e-mail: *molly.story@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

To understand use-related hazards, it is necessary to have an accurate and complete understanding of how a device will be used. Understanding and optimizing how people interact with technology is the subject of human factors engineering (HFE) and usability engineering (UE). HFE/UE considerations that are important to the development of medical devices include three major components of the device-user system: (1) Device users, (2) device use environments, and (3) device user interfaces.

For safety-critical technologies such as medical devices, the process of eliminating or reducing design-related use problems that contribute to or cause unsafe or ineffective medical treatment is part of a process for controlling overall risk. For devices where harm could result from ''use errors,'' the dynamics of user interaction are safety-related and should be components of risk analysis and risk management. By incorporating these considerations into the device development process, manufacturers can reduce the overall risk level posed by their devices, thus decreasing adverse events associated with the device, and avoid potential device recalls.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the Agency's current thinking on human factors engineering for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability is available for all CDRH guidance documents at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design.'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1757 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 17, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–15570 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0443]

Scientific Evaluation of Modified Risk Tobacco Product Applications; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products is announcing a public workshop to obtain input on specific issues associated with the scientific evaluation of modified risk tobacco product (MRTP) applications. The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) establishes a requirement for persons to obtain an order from FDA before they can introduce or deliver for introduction into interstate commerce MRTPs and outlines the requirements that must be met before FDA will issue such an order. The Tobacco Control Act also directs FDA to get input from appropriate scientific and medical experts on the design and conduct of studies and surveillance required for assessment and ongoing review of MRTP applications. The purpose of the public workshop is to create a forum for appropriate scientific and medical experts and other interested stakeholders to provide input on these topics. FDA will take the information it obtains from the public workshop into account as it determines how best to implement the MRTPs provisions of the Tobacco Control Act. FDA is also opening a public docket to receive comments on these topics.

DATES: *Dates and Times:* The public workshop will be held on August 25, 2011, from 8:30 a.m. to 5:30 p.m., and on August 26, 2011, from 8:30 a.m. to 4 p.m. Individuals who wish to make a presentation at the public workshop must register by close of business on August 3, 2011. Submit either electronic or written comments to the docket by September 23, 2011.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: *Contact Person:* Anuja Patel, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 4), FAX: 240–276–3761, e-mail: *workshop.CTPOS@fda.hhs.gov.*

Registration to Attend the Workshop and Requests for Oral Presentation: If you wish to attend the workshop or make an oral presentation at the workshop, please e-mail your registration to *workshop.CTPOS@fda.hhs.gov* by close of business on August 3, 2011. Those without e-mail access may register by contacting Anuja Patel (*see Contact Person*). Please provide contact information for each attendee, including name, title, affiliation, address, e-mail address, and telephone number. Registration is free and will be on a first-come-first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at *http://www.fda.gov/TobaccoProducts/default.htm.*

An open comment session will be held during the public workshop on August 25, 2011, from 11 a.m. to 12:30 p.m., during which comments from the public will be accepted. If you would like to make an oral presentation during the open comment session, you must indicate this at the time of registration. FDA has included questions for comment in section II of this document. You should identify the question number(s) you will address in your presentation and the approximate time requested for your presentation.

FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make a formal presentation must check in at the registration table by 10 a.m. on August 25, 2011. In addition, we strongly encourage submitting comments to the docket (*see Comments*).

If you need special accommodations because of a disability, please contact Anuja Patel (see *Contact Person*) at least 7 days before the workshop.

Comments: Regardless of attendance at the public workshop, interested persons may submit comments on any questions for comment in section II of this document by September 23, 2011. 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.