FEDERAL COMMUNICATIONS COMMISSION

[FRS 17148]

Wireless E911 Location Accuracy Requirements

AGENCY: Federal Communications Commission.

ACTION: Petitions for reconsideration.

SUMMARY: The Association of Public-Safety Communications Officials-International, Inc. (APCO) and CTIA have each filed a Petition for Reconsideration in the Commission’s Wireless E911 Location Accuracy rulemaking proceeding, PS Docket 07–114.

DATES: Oppositions to the Petitions must be filed on or before November 3, 2020. Replies to an opposition must be filed on or before November 13, 2020.


FOR FURTHER INFORMATION CONTACT: John Evanoff, john.evanoff@fcc.gov, of the Public Safety and Homeland Security Bureau, Policy and Licensing Division, (202) 418–0848.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s document, released on October 8, 2020 (DA 20–1175). The Petitions may be accessed online via the Commission’s Electronic Comment Filing System at: https://www.fcc.gov/ecfs/. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA. Agencies and the public are encouraged to provide written comments regarding the scope of the EA. Comments must be received on or before November 18, 2020.

ADDRESSES: Submit comments in response to Notice—PBS–2020–10, by any of the following methods:
  • Mail: General Services Administration, Portfolio Division ATTN: VA Hampton Roads CBOC. General Services Administration, 100 South Independence Mall W, Philadelphia, PA 19106, Room 2191.
  • Email: VA.HamptonRoads.CBOC@gsa.gov.

FOR FURTHER INFORMATION CONTACT: General Services Administration, Mid-Atlantic Region, ATTN: Todd Gledek, PHONE: (215) 606–1757, EMAIL: VA.HamptonRoads.CBOC@gsa.gov.

SUPPLEMENTARY INFORMATION:
Background

The General Services Administration intends to prepare an Environmental Assessment (EA) to analyze the potential impacts resulting from the development of a new leased Community-Based Outpatient Clinic (CBOC) in the Hampton Roads region of southeast Virginia. The new site is intended to support the growing veteran population in the Hampton Roads region by providing increased levels of health and wellness services. While an existing 13,000 square foot CBOC is in operation in Virginia Beach, Virginia, this site cannot support necessary expansion to support increased levels of health care service.

The Proposed Action would consist of acquiring property to construct a stand-alone building to provide primary care, mental health, and eye clinic services. A selected developer would be responsible for acquiring the selected site, constructing the proposed facility, and assuming ownership and maintenance of the site.

Alternatives Under Consideration

The EA will consider Action Alternatives for the proposed CBOC on available sites offered by developers within the Hampton Roads region as well as the No Action Alternative. The Action Alternatives will analyze the development and operation of the CBOC. The CBOC would be developed to support identified program requirements for approximately 186,200 square feet within two contiguous floors and 1,050 parking spaces within a contiguous site. Under the No Action Alternative, no CBOC would be developed.

Scoping Process

Scoping will be accomplished through public notifications in the Virginia Pilot and direct mail correspondence to appropriate federal, state, and local agencies; surrounding property owners; and private organizations and citizens who have previously expressed or are known to have an interest in the Project.

The primary purpose of the scoping process is for the public to assist GSA in determining the scope and content of the environmental analysis. Dated: October 9, 2020.

John Calhoun,
Director, Portfolio Management Division (3PT).

[FR Doc. 2020–23038 Filed 10–16–20; 8:45 am]
BILLING CODE 6820–89–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Notice to Public of Website Location of Center for Devices and Radiological Health Fiscal Year 2021 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post two lists of
guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in fiscal year (FY) 2021. In addition, FDA has established a docket where interested persons may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide any other comments that could benefit the CDRH guidance program and its engagement with stakeholders. This feedback is critical to the CDRH guidance program to ensure that we meet stakeholder needs.

DATES: Submit either electronic or written comments by December 18, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 18, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 18, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2012–N–1021 for “Notice to Public of Website Location of CDRH Fiscal Year 2021 Proposed Guidance Development.” Received comments, those filed in a timely manner (see ADDRESSES), 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:
Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5466, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations on the Medical Device User Fee Amendments of 2012, Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA agreed to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. Among these commitments included:
• Annually posting a list of priority medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the “A-list”), and
• Annually posting a list of device guidance documents that the Agency intends to publish, as the Agency’s guidance-development resources permit each fiscal year (the “B-list”).

The Medical Device User Fee Amendments of 2017 (MDUFA IV), FDA Reauthorization Act of 2017 (Pub. L. 115–52), maintained these commitments.

In addition, to ensure that final guidance documents continue to provide stakeholders with the Agency’s current thinking, CDRH annually conducts a staged review of previously issued final guidances in collaboration with stakeholders. CDRH intends to annually provide lists of previously issued final guidances that are subject to review through FY 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2022, CDRH expects to provide a list of the final guidance documents that issued in 2012, 2002, 1992, and 1982; the annual notice for FY 2023 is expected to provide a list of the final guidance documents that issued in 2013, 2003, 1993, and 1983, and so on.

FDA welcomes comments on any or all of the guidance documents on the
lists as explained in 21 CFR 10.115(f)(5). FDA has established Docket No. FDA–2012–N–1021 where comments on the FY 2021 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see ADDRESSES). FDA believes this docket is a valuable tool for receiving information from interested persons. FDA anticipates that feedback from interested persons will allow CDRH to better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

In addition to posting the lists of prioritized device guidance documents, CDRH has identified as a priority, and has devoted resources to, finalization of draft guidance documents. To assure the timely completion or reissuance of draft guidances, in FY 2015 CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, reopen the comment period, or issue new draft guidance on the topic for 80 percent of the documents within 3 years of the close of the comment period and for the remaining 20 percent, within 5 years. As part of MDUFA IV commitments, FDA reaffirmed this commitment, as resources permit.

Fulfillment of these commitments will be reflected through the issuance of updated guidance on existing topics, withdrawal of guidances that no longer reflect FDA’s current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

II. CDRH Guidance Development Initiatives

A. Metrics for FY 2020 A-List and B-List Publication

Stakeholder feedback on guidance priorities is important to ensure that the CDRH guidance program meets the needs of stakeholders. The feedback received on the FY 2020 list was mostly in agreement, and CDRH continued to work toward issuing the guidances on this list. Some guidances requested for inclusion in the FY2020 list by stakeholders have been included as part of the FY 2021 list. In FY 2020, CDRH published 14 of 27 guidances on the FY 2020 list (12 from the A-list, 2 from the B-list). In addition, FDA is committed to providing timely guidance to support response to the Coronavirus Disease 2019 (COVID–19) pandemic. As such, FDA has shifted resources to issue 23 guidances and 11 guidance revisions in FY 2020.

B. Finalization of Draft Guidance Documents

Of the 23 draft guidances issued in FY 2015, CDRH finalized 91 percent within 3 years of the comment period close and 91 percent within 5 years. In addition, in FY 2020, two draft guidances issued prior to October 1, 2014, remain for which no action has been taken yet, and CDRH has been continuing to work towards taking an action on these remaining draft guidances.

Looking forward, in FY 2021, CDRH will strive to finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2015.

C. Applicability of Previously Issued Final Guidance

At the website where CDRH has posted the “A-list” and “B-list” for FY 2021, CDRH has also posted a list of final guidance documents that issued in 2011, 2001, 1991, and 1981 for our annual review of previously issued final guidances. CDRH is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH will consider the comments received from this retrospective review when determining priorities for updating guidance documents and will revise these as resources permit.

Consistent with the Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda website, feedback on any guidance is appreciated and will be considered.

In FY 2020, CDRH received comments regarding guidances issued in 2010, 2000, 1990, and 1980 and has withdrawn 52 guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency’s current thinking. The revision of several guidance documents is also being considered as resources permit.

III. Website Location of Guidance Lists

This notice announces the website location of the document that provides the A- and B-lists of guidance documents, which CDRH is intending to publish during FY 2021. To access these two lists, visit FDA’s website at https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidance-development. We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (e.g., newly identified safety issues). The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1359]

Sugars that Are Metabolized Differently Than Traditional Sugars

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or we) is establishing a docket and invites information about and comments on the nutrition labeling of sugars that are metabolized differently than traditional sugars. We are taking this action to inform our regulatory approach to these distinctly metabolized sugars to promote the public health and help consumers make informed dietary decisions.

DATES: Submit either electronic or written comments on the notice by December 18, 2020.

ADDRESSES: You may submit comments as follows. Please note that late,