ACTION: Notice of availability; request for comments.

SUMMARY: As part of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency By Promoting Greater Access to the Agency's Compliance and Enforcement Data.'' This report includes eight draft proposals to make FDA's publicly available compliance and enforcement data more accessible and user-friendly. FDA is seeking public comment on these draft proposals. The Transparency Task Force will ultimately recommend specific draft proposals to the Commissioner of Food and Drugs (the Commissioner) for consideration based on the comments it receives, the feasibility of the draft proposal, relative priority, and available resources.

DATES: Submit either electronic or written comments by December 2, 2011.

ADDRESSES: 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 docket number found in brackets at the heading of this document and the draft proposal(s) that the comments address.

FOR FURTHER INFORMATION CONTACT: Lisa M. Dwyer, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4228, Silver Spring, MD 20993, 301–796–4709, FAX: 301–847–8616, e-mail: *lisa.dwyer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a report entitled ''FDA Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency By Promoting Greater Access to the Food and Drug Administration's Compliance and Enforcement Data.'' FDA is responsible for a broad range of compliance and enforcement activities. Increasing the transparency of these activities allows the public to better understand the Agency's decisions, and it promotes accountability of the Agency and the regulated industry.

On January 18, 2011, President Obama issued a Presidential Memorandum on Regulatory Compliance, 76 FR 3825 (January 21, 2011), requiring Federal Agencies to make publicly available compliance information easily accessible, downloadable, and searchable online. In that memorandum, the President highlighted the achievements of the Environmental Protection Agency (EPA) and the Department of Labor (DOL) in developing Web sites (*http://www.epa-echo.gov* and *http://ogesdw.dol.gov,* respectively) that make their regulatory compliance information more accessible to the public.

FDA responded to the Presidential Memorandum on Regulatory Compliance in a memorandum to the Department of Health and Human Services (HHS), on May 6, 2011 (FDA Response). The FDA Response summarized the actions that the Agency already had implemented, as well as those that were underway or proposed, to make its regulatory compliance and enforcement information more accessible to the public. FDA took those actions in response to the Presidential Memorandum on Transparency and Open Government, 74 FR 4685 (January 26, 2009), which the President issued in January 2009, and as part of FDA's own Transparency Initiative, which the Commissioner, Dr. Margaret A. Hamburg, launched in June 2009.

In the FDA response, the Agency also committed to examining the manner in which EPA and DOL disclose compliance and enforcement information to determine whether there are additional steps FDA could take to make comparable information more accessible. Specifically, FDA stated that it would: (1) Within 150 days (by October 3, 2011), issue proposals for public comment, if it concluded that there were additional opportunities to increase the transparency of its compliance and enforcement data and (2) within 270 days (January 31, 2012), determine whether to adopt those proposals.

After meeting with EPA and DOL to discuss their methods for making compliance and enforcement data more accessible, FDA has determined that there are additional steps that it could take to make its own information more transparent and accessible to the public. This report contains FDA's draft proposals for public comment.

II. 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 the draft proposal(s) which your comment addresses by the number assigned to the proposal. 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: September 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25354 Filed 10–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0270; formerly Docket No. 2007N–0357]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2012 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web site location where the Agency will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993–0002, 301–796–5678.

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting

a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web site location of the list of guidances on which CDRH is intending to work over the next fiscal year (FY). We note that the Agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH's experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This will be the fifth annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a docket where comments about the FY 2012 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued by FDA under its good guidance practices (21 CFR 10.115(f)(5)). This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each FY from 2008 to 2012. To access the list of the guidance documents CDRH is considering for development in FY 2012, visit FDA's Web site *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm*.

II. Request for 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: September 29, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–25507 Filed 10–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Preparation for International Conference on Harmonization Steering Committee and Expert Working Group Meetings in Seville, Spain; Regional Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Steering Committee and Expert Working Group Meetings in Seville, Spain'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Seville, Spain. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Seville, Spain, scheduled on November 5 through 10, 2011, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The public meeting will be held on October 25, 2011, from 2 p.m. to 4 p.m.

Location: The public meeting will be held at the Washington Theater room at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: All participants must register with Kimberly Franklin, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, e-mail: *Kimberly.Franklin@fda.hhs.gov,* or FAX: 301–595–7937.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to the contact person (see *Contact Person*) by October 21, 2011.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 3:30 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person (see *Contact Person*) by October 21, 2011, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, telephone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

If you need special accommodations due to a disability, please contact Kimberly Franklin (see *Contact Person*) at least 7 days in advance.

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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. 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 Division of Freedom of Information (ELEM–1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint