Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: December 11, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–30123 Filed 12–17–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0575]

Incorporation of New Science Into Regulatory Decisionmaking Within the Center for Devices and Radiological Health; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled: ''Incorporation of New Science Into Regulatory Decisionmaking Within the Center for Devices and Radiological Health.'' The purpose of the public meeting is to identify strategies and means for incorporating new science into the regulatory decisionmaking process within the agency's Center for Devices and Radiological Health (CDRH). New science may include novel technologies or novel uses of existing technologies, evolving information and knowledge, or new methods to support decisionmaking. FDA is seeking input on a number of specific questions regarding how CDRH should anticipate and respond to new or evolving scientific knowledge in a manner that is consistent with our mission to protect and promote the public health, and requests comments on this topic.

Dates and Time: The public workshop will be held on February 9, 2010, from 8 a.m. to 5 p.m. Persons interested in attending the meeting must register by 5 p.m. on February 3, 2010.

Location: The public meeting will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Maggie Dietrich, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993–0002, 301–796–5094, FAX: 301–847–8510, e-mail: *maggie.dietrich@fda.hhs.gov*.

Registration: Register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list). Provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. Registration requests should be received by February 3, 2010. 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 based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

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

Comments: FDA is holding this public meeting to obtain information on a number of specific questions regarding how CDRH should anticipate and respond to new or evolving scientific knowledge in a manner that is consistent with FDA's mission to protect and promote the public health. The deadline for submitting comments regarding this public meeting is February 24, 2010.

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments. Submit 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*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Please also indicate the specific question(s) addressed. (See section II 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's CDRH uses science to guide our regulatory decisions, including those related to premarket approval or clearance, postmarket oversight, and compliance.

CDRH faces unique challenges in that the products we regulate are constantly changing, either through incremental or disruptive advances. Simultaneously, our understanding of the products we oversee is subject to change as we obtain new scientific information or develop new methods to assess existing data.

Given the ever-changing environment in which we operate, CDRH's regulatory decisionmaking process must be able to adapt as science evolves and as new information emerges about the risks or benefits of particular medical devices or radiation-emitting electronic products. For example, in some cases, new information gathered about the risk-benefit profile of a device on the market may justify requiring additional data on similar types of devices during premarket review, in order to provide sufficient confidence in the product's safety and effectiveness. At the same time, the center seeks to foster innovation by providing industry with a reasonable degree of predictability in our regulatory pathways. Determining the optimal way to anticipate and respond to new science is an important challenge, and the center seeks public input on how to best address it.

CDRH has formed an internal Task Force on Utilization of New Science in Regulatory Decisionmaking to review how the center uses science in our regulatory decisionmaking process, and to make recommendations for enhancements. The principal goals of the Task Force are: (1) To propose systems that will allow CDRH to be ''predictably adaptive'' to new science; and (2) to identify proactive steps that CDRH can take to keep staff abreast of new science and increase our technical competence and analytic capability in order to enhance our decisionmaking.

The notion of ''predictable adaptability'' refers to having the flexibility to appropriately respond to changes in science, while doing so through a reasonably consistent process. Given that scientific knowledge is continually changing, the model of being ''predictable'' by always requiring the same type and level of scientific evidence to justify decisions will not necessarily suffice. As the scientific landscape changes, the kind of information we need in order to make well-supported decisions may change. In the past, CDRH has sometimes incorporated new science into our regulatory decisionmaking on an ad hoc, non-transparent basis. Such an approach can result in inconsistent regulatory expectations and less predictable decisionmaking.

CDRH seeks to move toward a different model of predictability: Creating and adhering to clear procedures for adapting to new science, and applying a consistent rationale for doing so in as timely and transparent a manner as is appropriate and feasible. In order to achieve this goal, the center

will need to identify how and when to adapt to new science, with a full consideration of the nature of the science itself, public health implications, and our statutory and regulatory framework.

II. Public Meeting

As one step towards establishing the center's approach for incorporating new science in regulatory decisionmaking, CDRH will hold a public meeting to discuss the issues the Task Force is considering. The objective of the meeting will be to hear input on these issues from a broad range of external constituencies, including industry representatives, consumer and patient advocates, academic experts, other members of Government, and the general public.

To focus the center's strategies, CDRH requests feedback related to the following questions, which will serve as the basis for discussion at the public meeting:

A. Adapting to New Scientific Information

(1) When CDRH gains new scientific information about a particular product or type of product, what should the criteria be for changing CDRH's expectations of the evidence necessary for pre- or postmarket regulatory decisions, keeping in mind our mission to protect and promote the public health, as well as our statutory and regulatory framework? What are potential ''triggers'' for making such changes?

(2) When such changes are warranted, how should the center communicate them to industry, consumers, and other external constituencies? Should CDRH have a new regulatory paradigm for communicating with outside parties?

(3) When such changes are warranted, how should CDRH apply them to devices currently under review?

(4) When such changes are warranted, how should CDRH apply them to products currently on the market? For example, how should CDRH treat ''first-generation'' products as new and improved versions are developed?

B. Adapting to Novel Technologies or Novel Uses of Existing Technologies

(1) Assessing the safety and effectiveness of a novel technology can be challenging because the extent of information on and the level of understanding of the technology's risk-benefit profile or manufacturing process is less mature than that of a technology for which there is extensive ''real-world'' experience. What steps should CDRH take to assure that novel technologies or novel uses of existing technologies are safe and effective, without creating barriers to innovation, keeping in mind our statutory and regulatory framework?

C. Enhancing CDRH's Technical Competence and Analytical Capability

(1) With current resources, what proactive steps should CDRH take to address gaps in staff-members' knowledge about new science and reduce uncertainty in science-based regulatory decisionmaking?

During the meeting, there will be a moderated discussion between CDRH staff and invited experts from the private and public sectors about the questions presented in this document. The invited participants will not be asked to develop consensus recommendations, but rather to provide their individual perspectives. The topics for discussion will be presented in conjunction with hypothetical case studies for consideration. There will also be an opportunity for general attendees to provide feedback on the discussion topics during periodic open sessions.

In advance of the meeting, additional information, including the case studies, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available on FDA's Medical Devices Web site at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list), along with the agenda for the meeting.

Transcripts: Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at *http://www.regulations.gov*.

Dated: December 11, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–30114 Filed 12–17–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3221–N]

Medicare Program; Physician Quality Reporting Initiative (PQRI): Listening Session-February 2, 2010.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session to discuss the Physician Quality Reporting Initiative (PQRI). The purpose of the listening session is to solicit input from participating stakeholders on—

- The individual quality measures and measures groups (for example, suggestions for new measures groups or suggestions for the composition of existing measures group(s) being considered for possible inclusion in the proposed set of quality measures for use in the 2011 PQRI program and;
- Key components of the design of the PQRI program, such as possible reporting mechanisms, reporting periods, criteria for satisfactory reporting, the group practice reporting option, and public reporting of 2011 PQRI data.

Measure developers, eligible professionals, professionals associations, such as medical specialty societies, and other interested stakeholders are invited to participate, in person or by teleconference.

The opinions and alternatives provided during this meeting will assist us as we evaluate the PQRI program for 2011. We anticipate posting a summary of the individual quality measures and measures groups for possible inclusion in the proposed set of quality measures as well as possible program design options under consideration for use in the 2011 PQRI program on the PQRI section of the CMS Web site at *http://www.cms.hhs.gov/PQRI* by January 18, 2010.

The meeting is open to the public, but attendance is limited to space and teleconference lines available.

DATES: *Meeting Date:* The listening session will be held on Tuesday, February 2, 2010 from 10 a.m. until 4:30 p.m. Eastern Standard Time (E.S.T).

Meeting Registration and Request for Special Accommodations Deadline: Registration opens on Monday, December 21, 2009. For security reasons, registration must be completed no later than 5 p.m. E.S.T. on Wednesday, January 27, 2010. Requests