recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number_____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Call the Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10482 Evaluation of the Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Incentive Program

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Incentive Program; *Use:* The Physician Quality Reporting System (PQRS) was first implemented in 2007 as an incentive for voluntary reporting of quality measures in accordance with a section of the Tax Relief and Health Care Act of 2006. The PQRS was further extended and enhanced by legislation such as the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (MMSEA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). A number of changes have been made to the PQRS, including group measures, the group reporting option, and additional measures. The PQRS was extended further with the enactment of MMSEA. The MMSEA provided professionals greater flexibility for participating in the PQRS for 2008 and 2009 by authorizing us to establish alternative reporting criteria and alternative reporting periods for the reporting measures groups and for the submission of data on the PQRS quality measures through clinical data registries. The MIPPA, enacted in July 2008, made the PQRS program permanent, further enhanced the PQRS, and established a new standalone incentive program for successful electronic prescribers.

The eRx Incentive Program, the other program being evaluated in this project, was first implemented in 2009. The eRx is another incentive reporting program that uses a combination of incentive payments and payment adjustments to encourage eRx by eligible professionals. The program provides an incentive payment to practices with eligible professionals who successfully e-prescribe for covered Physician Fee Schedule services furnished to Medicare Part B Fee-For-Service (FFS) beneficiaries. Eligible professionals do not need to participate in PQRS to participate in the eRx Incentive Program.

In support of an evaluation the PQRS and the eRx Incentive Program, we will conduct three surveys. The surveys will include: Medicare beneficiaries, eligible professionals, and administrators. This evaluation is designed to determine how well the PQRS and the eRx Incentive Program are contributing to better and affordable health care for Medicare beneficiaries. The PQRS is a voluntary reporting program that provides an incentive payment to eligible professionals who satisfactorily report data on quality measures. We use quality measures to promote improvements in care delivery and payment and to increase transparency. The PQRS program rewards eligible professionals based on a percentage of the estimated Medicare Physician Fee Schedule of their allowed Part B charges if they meet the defined reporting requirements. The PQRS was initially referred to as the Physician Quality Reporting Initiative (PQRI). *Form Number:* CMS–10482 (OCN: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Individuals and households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,350; *Total Annual Responses:* 6,350; *Total Annual Hours:* 2,545. (For policy questions regarding this collection contact Lauren Fuentes at 410–786–2290. For all other issues call 410–786–1326.)

Dated: June 11, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–14174 Filed 6–13–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0790]

Food and Drug Administration Decisions for Investigational Device Exemption Clinical Investigations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.'' This guidance document was initially issued in draft on November 10, 2011, and was developed to promote the initiation of clinical investigations to evaluate medical devices under FDA's IDE regulations. The guidance was also intended to provide clarification

regarding the regulatory implications of the decisions that FDA may render based on review of an IDE and to provide a general explanation of the reasons for those decisions. This guidance has been revised and is being reissued for comment because the Food and Drug Administration Safety and Innovation Act (FDASIA), which became law on July 9, 2012, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to specify certain situations in which FDA cannot disapprove an IDE. 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 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 either electronic or written comments on the draft guidance by September 12, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations'' 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 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. 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: Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1108, Silver Spring, MD 20993–0002, 301–796–6356; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA approval of an IDE submission allows the initiation of a clinical investigation of a significant risk device. This guidance is intended to provide clarification regarding the regulatory implications of the decisions that FDA may render based on review of an IDE and to provide a general explanation of the reasons for those decisions. In an effort to promote timely initiation of enrollment in clinical investigations in a manner that protects study subjects, FDA has developed methods to allow a clinical investigation of a device to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. These mechanisms, including approval with conditions, staged approval, and communication of outstanding issues related to the IDE through study design considerations and future considerations, are described in this guidance.

FDA has traditionally referred to IDE approvals that have conditions as ''conditional approvals.'' FDA believes that the term ''approval with conditions'' is more appropriate because the term conveys that the IDE has been approved and the study may begin without awaiting further FDA review. An IDE may be approved with conditions if FDA has determined that, despite outstanding issues, the information provided is sufficient to justify human clinical evaluation of the device and the proposed study design is acceptable with regard to protection of study subjects.

FDA may now also communicate ''future considerations'', which are issues and recommendations that FDA believes the sponsor should consider in preparation for a marketing application or a future clinical investigation. Future considerations are intended to provide helpful, non-binding advice to sponsors regarding important elements of the future application that the IDE may not specifically address. FDA is considering whether future considerations should be communicated in our IDE decision letters or whether they should be sent to the sponsor in a separate communication. The Agency is specifically seeking comment on this issue.

Consistent with the November 2011 draft guidance, this guidance also proposes two other mechanisms for approving studies or approving studies with conditions: ''Staged approval'' and ''staged approval with conditions,'' by which FDA may grant IDE approval or approval with conditions, while certain outstanding questions are answered concurrent with enrollment of a limited number of subjects in the clinical investigation. Staged approval and staged approval with conditions permit the clinical investigation to begin in a timely manner while maintaining appropriate subject protections. Staged approval or staged approval with conditions is most common for pivotal studies in which many subjects will be enrolled over an extended period of time, but may be applicable to other clinical investigations as well.

Section 601 of FDASIA amended section 520(g) of the FD&C Act (21 U.S.C. 360j(g)) to specify certain situations in which FDA cannot disapprove an IDE. Section 520(g)(4)(C) of the FD&C Act states that, consistent with section 520(g)(1), FDA shall not disapprove an IDE because: (1) The investigation may not support a substantial equivalence or de novo classification determination or approval of the device; (2) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or (3) an additional or different investigation may be necessary to support clearance or approval of the device. The draft guidance has been revised in light of this new provision and to introduce the communication to the sponsor of study design-related issues. If FDA believes that additional modifications to the study design are needed, which are unrelated to subject safety, for the study design to be adequate and ultimately support a marketing application, if that is the intent of the sponsor, these suggested modifications will be noted in the ''study design considerations'' section of FDA's letter. Sponsors are not required to modify the investigational plan to address study design considerations. However, if these considerations are not addressed, the study design may not support the study goals (e.g., a future marketing application). FDA is considering whether study design considerations should be communicated in our IDE decision letters or whether they should be sent to the sponsor in a separate communication. The Agency is specifically seeking comment on this issue.

Section 601 of FDASIA specifies certain situations in which FDA cannot disapprove an IDE. However, the Agency recognizes that some IDE sponsors may wish to determine whether the pivotal study design may support a marketing application if it is successfully executed and meets its stated endpoints without raising unforeseen safety concerns. To meet this

interest, FDA is proposing a new, voluntary program intended to encourage device manufacturers to engage with the Agency in the development of trial designs that may support a marketing approval or clearance. The Agency recognizes that this type of voluntary program will not likely be suitable for all IDE sponsors and does not intend that this program become a routine step prior to submission of an IDE. This program is not intended to replace or be a substitute for the Pre-Submission process (Refer to the draft guidance entitled ''Medical Devices: The Pre-Submission Program and Meetings with FDA Staff'' (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm,* which, when finalized, will represent FDA's current thinking on this topic).

This program, referred to as the ''Pre-Decisional IDE Process,'' is a voluntary approach to enable sponsors to obtain timely feedback from review staff on a near-final IDE application, with the opportunity for a midcycle interaction with the review team to promote clearer understanding and quicker resolution of major issues with device or subject safety as well as study design. The Pre-Decisional IDE process is different from the Pre-Submission process, which is appropriate for focused discussions with FDA early in device development or when nonclinical testing is underway. Pre-Submission discussions are generally limited in nature, as they focus on the proposed protocol and the specific questions for which the sponsor is requesting FDA feedback. Additionally, FDA does not typically review data from nonclinical bench, animal, or other studies when providing feedback on a clinical study protocol as part of a Pre-Submission. In contrast, Pre-Decisional IDEs will include data and full study protocols and reports where appropriate, and will be reviewed in a similar manner as an IDE, allowing for more complete and meaningful feedback from review staff. FDA intends to adhere to the feedback and decisions reached during the Pre-Decisional IDE review. FDA intends that modifications to our feedback will be limited to situations in which FDA concludes that the feedback given previously does not adequately address important issues materially relevant to a determination of safety or effectiveness that have been identified since the time of the Pre-Decisional IDE. In such cases, FDA should acknowledge a change in our advice, document the rationale for the change, and support the determination with appropriate management concurrence.

Although this process, as proposed, would occur over a 65-day timeframe (from submission of the Pre-Decisional IDE to complete FDA feedback, inclusive of the midcycle interaction), FDA believes that this process could result in faster approval without conditions of IDE submissions with study designs that are sufficiently robust to support market approval or clearance. Currently, many IDE submissions are approved with conditions only after an initial disapproval and submission of one or more responses, and may remain approved with conditions over many months while the outstanding issues are addressed. The Pre-Decisional IDE process is intended to reach an unconditional approval more quickly, and will help to address several commonly reported challenges in the initiation of clinical trials, such as delays in institutional review board approvals and reimbursement from third-party payers. In addition to seeking comments on the revised draft guidance as a whole, the Agency is specifically seeking comment on this new proposed program, as outlined in section 10 of the guidance.

As a result of this draft guidance, FDA, where appropriate, seeks to offer flexibility in how outstanding issues can be addressed to allow clinical investigations to commence without unnecessary delay, while ensuring that human subjects are adequately protected.

FDA issued this guidance document as draft on November 10, 2011. The Agency has considered the comments received during the comment period and incorporated modifications, as appropriate. This guidance has also been revised to reflect the changes to the FD&C Act described in this document and is being reissued in draft in order to solicit comment on these significant revisions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on FDA decisions for IDE clinical investigations. 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 for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations,'' you may either send an email 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 1783 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously 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 812 have been approved under OMB control number 0910–0078.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov*.

Dated: June 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14137 Filed 6–13–13; 8:45 am]

BILLING CODE 4160–01–P