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: Extension of a currently approved collection; Title of Information Collection: Medicare Quality of Care Complaint Form; Use: In accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) are required to conduct appropriate reviews of all written complaints submitted by beneficiaries concerning the quality of care received. The Medicare Quality of Care Complaint Form will be used by Medicare beneficiaries to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure pertinent information is obtained by QIOs to effectively process these complaints. Form Number: CMS–10287 (OMB control number: 0938–1102); Frequency: Occasionally; Affected Public: Individuals and Households; Number of Respondents: 3,500; Total Annual Responses: 3,500; Total Annual Hours: 583. (For policy questions regarding this collection contact Winsome Higgins at 410–786–1835.)

Dated: September 2, 2016.

William N. Parham, III, Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–21628 Filed 9–7–16; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2513]


AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled “ICH S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies—Questions and Answers.” The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. This question and answer (Q&A) guidance provides additional information to facilitate interpretation of the “S3A Guidance: The Assessment of Systemic Exposure in Toxicity Studies” (S3A guidance), especially to address the benefit and use of microsampling techniques in main study animals. The Q&A guidance is intended to provide points to consider before incorporating the microsampling method in toxicokinetic studies, and acknowledges the benefits (and some limitations) of the use of microsampling.

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 December 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, 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.”


Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the
from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers. In May 2016, the ICH Assembly endorsed the draft guidance entitled “ICH S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies—Questions and Answers” and agreed that the guidance should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the Safety Expert Working Group of the Safety Expert Working Group. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft Q&A guidance provides additional information to facilitate interpretation of the S3A guidance. The S3A guidance has been successfully implemented since 1994, and in recent years, analytical method sensitivity has improved, allowing microsampling techniques to be used in toxicokinetic assessment. This Q&A guidance focuses on points to consider before incorporating the microsampling method in toxicokinetic studies, acknowledges the benefits (and some limitations) of the use of microsampling for assessing toxicokinetics in main study animals, and acknowledges the overall important contribution of microsampling to the 3Rs benefits (Replacement, Reduction, and Refinement), by reducing or eliminating the need for toxicokinetic satellite animals.

The draft Q&A guidance is intended to apply to the majority of pharmaceuticals and biopharmaceuticals; however, for all types of molecules, consideration should be given on a case-by-case basis as to whether the sensitivity of the measurement method is appropriate with the small sample volumes available.

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 current thinking of FDA on ICH “S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies—Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access


Dated: September 1, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–21552 Filed 9–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 11, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written