be developed, or revised, after notice to
the public, with a 60-day comment
period, and in consultation with the
Advisory Commission on Childhood
Vaccines, appropriate health care
provider and parent organizations, and
the Food and Drug Administration. The
law also requires that the information
contained in the materials be based on
available data and information, be
presented in understandable terms, and
include:
(1) A concise description of the
benefits of the vaccine,
(2) A concise description of the risks
associated with the vaccine,
(3) A statement of the availability of
the National Vaccine Injury
Compensation Program, and
(4) Such other relevant information as
may be determined by the Secretary.

The vaccines initially covered under
the National Vaccine Injury
Compensation Program were diphtheria,
tetanus, pertussis, measles, mumps,
rubella, and poliomyelitis vaccines.
Since April 15, 1992, any health care
provider in the United States who
intends to administer one of these
covered vaccines is required to provide
copies of the relevant vaccine
information materials prior to
administration of any of these vaccines.
Since then, the following vaccines have
been added to the National Vaccine
Injury Compensation Program, requiring
use of vaccine information materials for
them as well: Hepatitis B, Haemophilus
influenzae type b (Hib), varicella
(chickenpox), pneumococcal conjugate,
rotavirus, hepatitis A, meningococcal,
human papillomavirus (HPV), and
seasonal influenza vaccines.

Instructions for use of the vaccine
information materials are found on the
CDC Web site at: http://www.cdc.gov/
vaccines/hcp/vis/index.html.

Revised Vaccine Information Materials

The hepatitis A and hepatitis B
vaccine information materials
referred to in this notice were
developed in consultation with the
Advisory Commission on Childhood
Vaccines, the Food and Drug
Administration, and parent and
healthcare provider organizations.
Following consultation and review of
comments submitted, the vaccine
information materials covering hepatitis
A and hepatitis B vaccines have been
finalized and are available to download
from http://www.cdc.gov/vaccines/hcp/vis/index.html or http://
www.regulations.gov (see Docket
Number CDC–2016–0015). The Vaccine
Information Statements (VIS) are
“Hepatitis A Vaccine: What You Need
to Know” and “Hepatitis B Vaccine:
What You Need to Know,” publication
date July 20, 2016.

With publication of this notice, by
November 1, 2016, all health care
providers must discontinue use of the
previous edition of each and provide
copies of these updated hepatitis A and
hepatitis B vaccine information
materials prior to immunization in
conformance with CDC’s August 9, 2016
Instructions for the Use of Vaccine
Information Statements.

Dated: September 1, 2016.

Sandra Cashman,
Executive Secretary, Centers for Disease
Control and Prevention.

[FR Doc. 2016–21573 Filed 9–7–16; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10287]

Agency Information Collection Activities: Proposed Collection;
Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing
an opportunity for the public to comment on CMS’ intention to collect
information from the public. Under the Paperwork Reduction Act of 1995 (the
PRA), federal agencies are required to publish notice in the Federal Register
concerning each proposed collection of information (including each proposed
extension or reinstatement of an existing collection of information) and to allow
60 days for public comment on the proposed action. Interested persons are
invited to send comments regarding our burden estimates or any other aspect
of this collection of information, including any of the following subjects: The
necessity and utility of the proposed information collection for the proper
performance of the agency’s functions; the accuracy of the estimated burden;
ways to enhance the quality, utility, and clarity of the information to be
collected; and the use of automated collection techniques or other forms of
information technology to minimize the information collection burden.

DATES: Comments must be received by November 7, 2016.

ADDRESSES: When commenting, please reference the document identifier or
OMB control number. To be assured consideration, comments and
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

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

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

SUPPLEMENTARY INFORMATION:

Contents

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–10287 Medicare Quality of Care
Complaint Form

Under the 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: 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, Rm. 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 docket, 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