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Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Performance Review Board Members

AGENCY: Centers for Disease Control and
Prevention (CDC), Department of Health
and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease
Control and Prevention (CDC) located
within the Department of Health and
Human Services (HHS) is publishing the
names of the Performance Review Board
Members who are reviewing
performance for Fiscal Year 2013.

FOR FURTHER INFORMATION CONTACT:
Sharon O'Brien, Deputy Director,
Executive and Scientific Resources
Office, Human Capital and Resources
Management Office, Centers for Disease
Control and Prevention, 4770 Buford
Highway NE., Mailstop K-15, Atlanta,
Georgia 30341, Telephone (770) 488-
1781.

SUPPLEMENTARY INFORMATION: Title 5,
U.S.C. 4314(c)(4) of the Civil Service
Reform Act of 1978, Public Law 95-454,
requires that the appointment of
Performance Review Board Members be
published in the **Federal Register**. The
following persons will serve on the CDC
Performance Review Boards or Panels,
which will oversee the evaluation of
performance appraisals of Senior
Executive Service members for the
Fiscal Year 2013 review period:

Christine Branche, Co-Chair
James Seligman, Co-Chair
Barbara Bowman
Janet Collins
Hazel Dean
Jane Gentleman
Joseph Henderson
Jennifer Parker
Tanja Popovic
Steve Redd
Tom Sinks
Kevin Smagh

Dated: November 8, 2013.

Stacey Hoffman,

Acting Director, Division of Executive
Secretariat, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1394]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing an
opportunity for public comment on the
proposed collection of certain
information by the Agency. 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 of an existing collection of
information, and to allow 60 days for
public comment in response to the
notice. This notice solicits comments on
the information collection in the
guidance for industry on special
protocol assessment.

DATES: Submit either electronic or
written comments on the collection of
information by January 17, 2014.

ADDRESSES: Submit electronic
comments on the collection of
information to [http://
www.regulations.gov](http://www.regulations.gov). Submit written
comments on the collection of
information 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 in the
heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA
PRA Staff, Office of Operations, Food
and Drug Administration, 1350 Piccard
Dr., PI50-400B, Rockville, MD 20850,
PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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.
"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 (44
U.S.C. 3506(c)(2)(A)) requires Federal
Agencies to provide a 60-day notice in

the **Federal Register** concerning each
proposed collection of information,
including each proposed extension of an
existing collection of information,
before submitting the collection to OMB
for approval. To comply with this
requirement, FDA is publishing notice
of the proposed collection of
information set forth in this document.

With respect to the following
collection of information, FDA invites
comments on these topics: (1) Whether
the proposed collection of information
is necessary for the proper performance
of FDA's functions, including whether
the information will have practical
utility; (2) the accuracy of FDA's
estimate of the burden of the proposed
collection of information, including the
validity of the methodology and
assumptions used; (3) ways to enhance
the quality, utility, and clarity of the
information to be collected; and (4)
ways to minimize the burden of the
collection of information on
respondents, including through the use
of automated collection techniques,
when appropriate, and other forms of
information technology.

Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910-0470)—Extension

The "Guidance for Industry on
Special Protocol Assessment" describes
Agency procedures to evaluate issues
related to the adequacy (e.g., design,
conduct, analysis) of certain proposed
studies. The guidance describes
procedures for sponsors to request
special protocol assessment and for the
Agency to act on such requests. The
guidance provides information on how
the Agency interprets and applies
provisions of the Food and Drug
Administration Modernization Act of
1997 and the specific Prescription Drug
User Fee Act of 1992 (PDUFA) goals for
special protocol assessment associated
with the development and review of
PDUFA products. The guidance
describes the following two collections
of information: (1) The submission of a
notice of intent to request special
protocol assessment of a carcinogenicity
protocol and (2) the submission of a
request for special protocol assessment.

Notification for a Carcinogenicity Protocol

As described in the guidance, a
sponsor interested in Agency
assessment of a carcinogenicity protocol
should notify the appropriate division
in FDA's Center for Drug Evaluation and
Research (CDER) or the Center for
Biologics Evaluation and Research
(CBER) of an intent to request special
protocol assessment at least 30 days