DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2014–N–0001]

Risk Communications Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communications Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on May 5 and 6, 2014, from 9 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Luis G. Bravo, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3274, Silver Spring, MD 20993–0002, 240–402–5274, email Luis.Bravo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

If you are unable to join us in person, we encourage you to watch the free Web cast. Visit the Risk Communication Advisory Committee Web site at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm. The link will become active shortly before the open session begins at 9 a.m.

Agenda: On May 5 and 6, 2014, the committee will meet to discuss methods for identifying the impact and increasing the reach of communications on topics of interest to consumers. The discussion will also address how FDA can evaluate whether its Consumer Updates (http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm) are reaching the targeted population, and whether they are increasing awareness and understanding of the key risk messages. The discussion will also assess whether the communications are having the intended impact on knowledge, behaviors and/or outcomes.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 28, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 18, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 3, 2014.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–04522 Filed 2–28–14; 8:45 am]

BILLING CODE 4160–01–P
open public hearing session, FDA may conduct a lottery to determine the
speakers for the scheduled open public hearing session. The contact person
will notify interested persons regarding their request to speak by April 21, 2014.

Persons attending FDA’s advisory committee meetings are advised that the
Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee
meetings and will make every effort to accommodate persons with physical
disabilities or special needs. If you require special accommodations due to
a disability, please contact Luis G. Bravo at least 7 days in advance of the
meeting.

FDA is committed to the orderly conduct of its advisory committee
meetings. Please visit our Web site at
http://www.fda.gov/Advisory
Committees/AboutAdvisoryCommittees/
umc111462.htm for procedures on
public conduct during advisory
committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5
U.S.C. app. 2).


Jill Hartzler Warner,
Acting Associate Commissioner for Special
Medical Programs.

[FR Doc. 2014–04523 Filed 2–28–14; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Health Resources and Services
Administration

Agency Information Collection
Activities: Submission to OMB for
Review and Approval; Public Comment
Request

AGENCY: Health Resources and Services
Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section
3507(a)(1)(D) of the Paperwork
Reduction Act of 1995, the Health
Resources and Services Administration
(HRSA) has submitted an Information
Collection Request (ICR) to the Office of
Management and Budget (OMB) for
review and approval. Comments
submitted during the first public review
of this ICR will be provided to OMB.
OMB will accept further comments from
the public during the review and
approval period.

DATES: Comments on this ICR should be
received within 30 days of this notice.

ADDRESSES: Submit your comments,
including the Information Collection
Request Title, to the desk officer for
HRSA, either by email to OIRA
 Submission@omb.eop.gov or by fax to

FOR FURTHER INFORMATION CONTACT: To
request a copy of the clearance requests
submitted to OMB for review, email the
HRSA Information Collection Clearance
Officer at paperwork@hrsa.gov or call
(301) 443–1984.

SUPPLEMENTARY INFORMATION:
Information Collection Request Title:
Organ Procurement and Transplantation
Network (OPTN) Application Form
OMB No.: 0915–0184 – Revision
Abstract: This is a request for OMB
approval for revisions of the application
documents used to collect information
for determining if the interested party is
compliant with membership and
transplant program requirements
contained in the Final Rule Governing
the Operation of the Organ Procurement
and Transplantation Network (OPTN),
“the OPTN final rule”.

Need and Proposed Use of the
Information: Membership in the OPTN is
determined by submission of
application materials to the OPTN (not
to HRSA) demonstrating that the
applicant meets all required criteria for
membership and transplant program
requirements and will agree to comply
with all applicable provisions of the
National Organ Transplant Act, as
amended, 42 U.S.C. 273, et seq. Section
1138 of the Social Security Act, as
amended, 42 U.S.C. 1320b-8 (section
1138) requires that hospitals in which
transplants are performed be members
of, and abide by, the rules and
requirements (as approved by the
Secretary of the HHS) of the OPTN as
a condition of participation in Medicare
and Medicaid for the hospital. Section
1138 contains a similar provision for the
organ procurement organizations
(OPOs) and makes membership in the
OPTN and compliance with its
operating rules and requirements (that
have been approved by the Secretary),
including those relating to data
collection, mandatory for all
transplant hospitals and OPOs. These applications
are developed to prompt submission of
all the information required to make
such membership approval decisions. In
addition, hospitals wishing to obtain
designation for particular (e.g., organ
specific) transplant programs must
submit applications to the OPTN.

Likely Respondents: Parties seeking
initial OPTN membership approval and
then maintenance of the existing OPTN
approval. Applicants will include:
every hospital seeking to perform organ
transplants; every non-profit
organization seeking to become an organ
procurement organization; and every
medical laboratory seeking to become a
histocompatibility laboratory. In
addition, there are other OPTN
member categories for organizations
and individuals who want to participate
in the organ transplant system and they
too are required to fill out an
appropriate application.

Burden Statement: Burden in this
case means the time expended by
persons to generate, maintain, retain,
disclose or provide the information
requested. This includes the time
needed to review instructions; to
develop, acquire, install and utilize
technology and systems for the purpose
of collecting, validating and verifying
information, processing and
maintaining information, and disclosing
and providing information; to train
personnel and to be able to respond to
a collection of information; to search
data sources; to complete and review
the collection of information; and to
transmit or otherwise disclose the
information. The total annual burden
hours estimated for this ICR are
summarized in the table below.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total responses</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>A New Transplant Member/Program Application—General</td>
<td>8</td>
<td>1</td>
<td>8</td>
<td>8</td>
<td>64</td>
</tr>
<tr>
<td>B Kidney (K) Designated Program Application</td>
<td>94</td>
<td>2</td>
<td>188</td>
<td>4</td>
<td>752</td>
</tr>
<tr>
<td>B Liver (L) Designated Program Application</td>
<td>73</td>
<td>2</td>
<td>146</td>
<td>4</td>
<td>584</td>
</tr>
<tr>
<td>B Pancreas (PA) Designated Program Application</td>
<td>56</td>
<td>2</td>
<td>112</td>
<td>4</td>
<td>448</td>
</tr>
<tr>
<td>B Heart (HR) Designated Program Application</td>
<td>43</td>
<td>2</td>
<td>86</td>
<td>4</td>
<td>344</td>
</tr>
<tr>
<td>B Lung (LU) Designated Program Application</td>
<td>50</td>
<td>2</td>
<td>100</td>
<td>4</td>
<td>400</td>
</tr>
</tbody>
</table>