DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2012–N–0001]

Pediatric 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: Pediatric
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 7, 2012, from 8 a.m. to 5:30
p.m. and May 8, 2012, from 8:30 a.m. to
11:30 a.m.

Location: Hilton Rockville Executive
Meeting Center, 1750 Rockville Pike,
Rockville, MD 20852.

Contact Person: Walter Ellenberg,
Office of Pediatric Therapeutics, Office
of the Commissioner, Food and Drug
Administration, 10903 New Hampshire
Ave., Bldg. 32, rm. 5154, Silver Spring,
MD 20993, 301–796–0885, or FDA
Advisory Committee Information Line,
1–800–741–8138 (301–443–0572 in the
Washington, DC area), and follow the
prompts to the desired center or product
area. Please call the Information Line for
up-to-date information on this meeting.

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 and
call the appropriate advisory committee
hot line/phone line to learn about
possible modifications before coming to
the meeting.

Agenda: On May 7, 2012, the
Pediatric Advisory Committee will meet
to discuss pediatric-focused safety
reviews, as mandated by the Best
Pharmaceuticals for Children Act and
the Pediatric Research Equity Act, for
Differin Lotion (adapalene), Dulera
Inhalation Aerosol (mometasone furoate
and formoterol fumarate), MultiHance
Injection (gadobenate dimeglumine),
Nasonex (mometasone furoate
monohydrate), Natazia (estriadiol
valerate and estriadiol valerate/
dienogest), Omnaris Nasal Spray
(ciclesonide), Protonix (pantoprazole),
Tamiflu (oseltamivir phosphate),
Taxotere (docetaxel) and Viread
(tenofovir disoproxil fumarate). The
committee will also receive an
Informational Update on FDA’s KidNet
pilot study.

On May 8, 2012, the Pediatric
Advisory Committee will meet
regarding the pediatric-focused safety
reviews, as mandated by the Pediatric
Research Equity Act, for Gardasil
Human Papillomavirus Quadrivalent
(Types 6, 11, 16, 18) Vaccine,
Recombinant, Isopto Carpine
(pilocarpine hydrochloride), Menveo
Meningococcal (Group A,C,Y, and W–
135) Oligosaccharide Diphtheria
CRM197 Conjugate Vaccine, Zylet
(Iotepredol etabonate and tobramycin)
and Zymaxid (gatifloxacin).

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 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 30, 2012. Oral
presentations from the public will be
scheduled between approximately 11:30
a.m. and 12:30 p.m. on May 7, 2012.
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
interested participants, and an
indication of the approximate time
requested to make their presentation on
or before April 20, 2012. Time allotted
for each presentation may be limited. If
the number of registrants requesting to
speak is greater than can be reasonably
accommodated during the scheduled
open public hearing session, FDA may
can 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 23, 2012.

Persons attending FDA’s advisory
commitee 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 Walter
Ellenberg 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).


Leslie Kux,
Acting Assistant Commissioner for Policy.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment
Request; Generic Clearance To
Conduct Voluntary Customer/Partner
Surveys

SUMMARY: In compliance with the
requirement of Section 3506(c)(2)(A) of
the Paperwork Reduction Act of 1995 to
provide opportunity for public comment
on proposed data collection projects, the
National Library of Medicine (NLM), the
National Institutes of Health (NIH) will
publish periodic summaries of proposed
projects to be submitted to the Office of
Management and Budget (OMB) for
review and approval.

Proposed Collection: Title: Generic
Clearance to Conduct Voluntary
Customer/Partner Surveys: Type of
Information Collection Request:
Extension of currently approved
collection [OMB No. 0925–0476, expiration
date 06/30/2012], Form
Number: NA; Need and Use of
Information Collection:: Executive
Order 12962 directed agencies that
provide significant services directly to
the public to survey customers to
determine the kind and quality of
services they want and their level of
satisfaction with existing services.
Additionally, since 1994, the NLM has
been a “Federal Reinvention Laboratory” with a goal of improving its
methods of delivering information to the
public. An essential strategy in