

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

### Gastrointestinal Drugs 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:* Gastrointestinal Drugs 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 31, 2012, from 8 a.m. to 4:30 p.m.

*Location:* FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., 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." Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, (301) 796-9001, Fax: (301) 847-8533, email: [GIDAC@fda.hhs.gov](mailto:GIDAC@fda.hhs.gov), 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 hotline/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss new drug application (NDA) 200-436, synthetic human secretin, sponsored by

Repligen Corporation, proposed for use with magnetic resonance imaging (MRI) to improve pancreatic duct visualization for the detection of duct abnormalities to enhance clinical decision making in patients with known or suspected pancreatitis.

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 May 16, 2012. 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 May 8, 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 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 May 9, 2012.

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 Minh Doan 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](http://www.fda.gov/AdvisoryCommittees/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).

Dated: March 19, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-6971 Filed 3-22-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

### Proposed Project: Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (OMB No. 0915-0346)—[Revision]

This is a revision to a data collection previously approved for the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (PNDP). Authorized under section 340A of the Public Health Service Act, as amended by Section 3510 of the Patient Protection and Affordable Care Act,

PNDP supports the development and operation of projects to provide patient navigator services to improve health outcomes for individuals with cancer and other chronic diseases, with a specific emphasis on health disparities populations. Award recipients are to use grant funds to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve in order to facilitate the care of those who are at risk for or who have cancer or other chronic diseases, including conducting outreach to health disparities populations.

As authorized by the statute, an evaluation of the outcomes of the program must be submitted to Congress. The purpose of these data collection instruments, including navigated patient data intake, VR-12 health status, patient navigator survey, patient navigator encounter/tracking log, patient medical record and clinic data, clinic rates (baseline measures), quarterly reports, and focus group discussion guides is to provide data to inform and support the Report to Congress for: the quantitative analysis of baseline and benchmark measures;

aggregate information about the patients served and program activities; and recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

A single instrument, the Client Opinion Form, has been added to this collection, resulting in an increase of 579.2 burden hours.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient Data Intake Form .....	4,827	1.0	4,827.00	0.50	2,413.50
VR-12 Health Status Form .....	4,827	2.0	9,654.00	0.12	1,158.50
Client Opinion Form .....	4,827	1.0	4,827.00	0.12	579.24
<i>SubTotal—Patient Burden</i> .....	<i>4,827</i>	.....	.....	.....	<i>4,151.22</i>
Patient Navigator Survey .....	46	1.0	46.00	0.20	9.20
Patient Navigator Encounter/Target Services Log .....	46	629.6	28,961.60	0.25	7,240.40
Patient Navigator Focus Group .....	46	1.0	46.00	1.00	46.00
<i>SubTotal—Patient Navigator Burden</i> .....	<i>46</i>	.....	.....	.....	<i>7,295.60</i>
Patient Medical Record and Clinic Data .....	10	482.7	4,827.00	0.17	820.59
Annual Clinic-Wide Clinical Performance Measures Report .....	5	1.0	5.00	8.00	40.00
Patient Navigator Cultural Competency Checklist .....	10	4.6	46.00	1.17	53.82
Patient Navigator/Health System Administrator Focus Group .....	50	1.0	50.00	1.00	50.00
Grantee Health Care Provider Focus Group .....	30	1.0	30.00	1.00	30.00
Social Service Provider Focus Group .....	50	1.0	50.00	1.00	50.00
Quarterly Report .....	10	4.0	40.00	1.00	40.00
<i>SubTotal—Grantee Burden</i> .....	<i>165</i>	.....	.....	.....	<i>1084.41</i>
<i>Totals</i> .....	<i>5,038</i>	.....	<i>53,409.60</i>	.....	<i>12,531.23</i>

Email comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 16, 2012.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2012-7085 Filed 3-22-12; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Nursing Research. The meeting will be open to the public as indicated below, with

attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Council for Nursing Research.

*Date:* May 15-16, 2012.

*Open:* May 15, 2012, 1 p.m. to 5:15 p.m.

*Agenda:* Discussion of Program Policies and Issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.

*Closed:* May 16, 2012, 9 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.

*Contact Person:* Yvonne E Bryan, Ph.D., Special Assistant to the Director, National Institute of Nursing, National Institutes of Health, 31 Center Drive, Room 5B-05, Bethesda, MD 20892, 301-594-1580, [bryany@mail.nih.gov](mailto:bryany@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.