Development of this guidance was facilitated by completion of the “Pharmacy Systems Under REMS Project: Standardizing REMS Information for Inclusion Into Pharmacy Systems Using Structured Product Labeling (SPL)” More information on this project—one of four predefined priority projects that are a part of the larger REMS Integration Initiative—can be found in the report “Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)” available at [http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM415751.pdf](http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM415751.pdf).

II. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access


Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA—2017–N–4866]

Pediatric Post-Marketing Pharmacovigilance and Drug Utilization Reviews; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to collect comments related to the pediatric post-marketing pharmacovigilance and drug utilization reviews of products posted between March 11, 2017, and September 12, 2017, on FDA’s Web site but not presented at the September 12, 2017, Pediatric Advisory Committee (PAC) meeting. These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

DATES: Submit either electronic or written comments by October 20, 2017.

ADDRESSES: You may submit your comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 20, 2017. The [https://www.regulations.gov](https://www.regulations.gov) electronic filing system will accept comments until midnight Eastern Time at the end of October 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: [https://www.regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://www.regulations.gov](https://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, you 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 [https://www.regulations.gov](https://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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the section of this notice to Nanobernetics, LLC (“Nanobernetics”) located in Maryland.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before September 20, 2017 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Jaime M. Greene, Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, Rm. 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530;