6366, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0493; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling; Draft Guidance for Industry.''

FDASIA (Pub. L. 112–144), amended the FD&C Act to add section 745A (21 U.S.C. 379k–1), entitled ''Electronic Format for Submissions.'' Section 745A(a)(1) of the FD&C Act requires that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the PHS Act (42 U.S.C. 262(a) or (k)) be submitted to FDA in electronic format no earlier than 24 months after FDA issues final guidance on electronic format for submissions. In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this draft guidance, announcing its determination that submission types identified in the guidance must be submitted electronically in the format specified in the guidance beginning 24 months after the issuance of the final guidance.

This draft guidance (and the technical specification documents it references) describes how certain REMS documents will be required to be submitted in electronic format using Structured Product Labeling (SPL) as outlined in the FDA ''Structured Product Labeling (SPL) Implementation Guide with Validation Procedures'' (available at *http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321876.pdf*). (FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register,** but Web sites are subject to change over time.) SPL is a Health Level 7 data standard used by FDA since 2005. For more information on how FDA interprets section 745A(a) of the FD&C Act, see the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section745A(a) of the Federal Food, Drug, and Cosmetic Act'' (available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384686.pdf*).

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*).

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

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: August 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–18506 Filed 9–1–17; 8:45 am]

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* 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.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *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.*
- 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 submission 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.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4866 for the ''Pediatric Post-Marketing Pharmacovigilance and Drug Utilization Reviews'' that have been posted on FDA's Web site between March 11, 2017, and September 12, 2017, but not presented at the September 12, 2017, PAC meeting. Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenneth Quinto, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5145, Silver Spring, MD 20993, 240–402–2221, email: *kenneth.quinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation.

FDA is establishing a public docket, Docket No. FDA–2017–N–4866, to receive input on pediatric post-marketing pharmacovigilance and drug utilization reviews posted between March 11, 2017, and September 12, 2017, available on FDA's Web site at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm,* but not presented at the September 12, 2017, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA–2017–N–4866. The docket will open on October 9, 2017, and remain open until October 20, 2017. These pediatric post-marketing pharmacovigilance and drug utilization reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

1. GRASTEK (Timothy Grass Pollen Allergen Extract) Tablet for Sublingual Use
2. ORALAIR (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Tablet for Sublingual Use

Center for Drug Evaluation and Research

1. ALOXI (palonosetron hydrochloride)
2. ARNUITY ELLIPTA (fluticasone furoate)
3. ASMANEX HFA and ASMANEX TWISTHALER (mometasone furoate inhalation)
4. CYMBALTA (duloxetine)
5. EMSAM (selegiline transdermal system)
6. LATISSE (bimatoprost ophthalmic solution) 0.03%
7. NAMENDA (memantine hydrochloride) and NAMENDA XR (memantine hydrochloride) extended-release
8. PRIFTIN (rifapentine)
9. REYATAZ (atazanavir)
10. TACLONEX (betamethasone dipropionate/calcipotriene hydrate) Topical Suspension 0.064%/0.005% and TACLONEX (betamethasone dipropionate/calcipotriene hydrate) Topical Ointment 0.064%/0.005%
11. ZETONNA (ciclesonide)

Dated: August 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18690 Filed 9–1–17; 8:45 am]

BILLING CODE 4164–01–P

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 **SUPPLEMENTARY INFORMATION** 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;