Application No.	Drug	Applicant
ANDA 074801	Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL.	Do.
ANDA 075385	Buspirone HCl Tablets USP, 5 mg, 10 mg, and 15 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075453	Doxazosin Tablets USP, EQ 1 mg base, EQ 2 mg base, EQ 4 mg base, and EQ 8 mg base.	Do.
ANDA 076883	Sotalol HCl Tablets USP, 80 mg, 120 mg, and 160 mg	Teva Pharmaceuticals USA, Inc.
ANDA 077052	Citalopram Hydrobromide Tablets, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Sun Pharmaceutical Industries, Inc.
ANDA 077937	Meloxicam Tablets, 7.5 mg and 15 mg	Do.
ANDA 078081	Amlodipine Besylate Tablets, EQ 2.5 mg base, EQ 5 mg base, and EQ 10 mg base.	Do.
ANDA 078158	Fosphenytoin Sodium Injection USP, EQ 50 mg Phenytoin Soudium/mL.	Hospira, Inc.
ANDA 078483	Zolpidem Tartrate Extended-Release Tablets USP, 6.25 mg and 12.5 mg.	Synthon Pharmaceuticals, Inc., 1007 Slater Rd., Suite 150, Durham, NC 27703.
ANDA 080136	Isoniazid Tablets, 100 mg	Sun Pharmaceutical Industries, Inc.
ANDA 080209	Prednisone Tablets USP, 5 mg	Contract Pharmacal Corp., c/o SciRegs International Inc., 6333 Summercrest Dr., Columbia, MD 21045.
ANDA 080224	Sorbitol; Mannitol Irrigation Solution, 2.7 g/100 mL; 540 mg/100 mL.	Hospira, Inc.
ANDA 083345	Potassium Chloride for Injection Concentrate USP, 1 milliequivalent (mEQ)/mL, 1.5 mEQ/mL, and 2 mEQ/mL.	Do.
ANDA 083808	Quinidine Sulfate Tablets USP, 200 mg	Contract Pharmacal Corp., c/o SciRegs International Inc.
ANDA 084623	Chlordiazepoxide HCl Capsules USP, 10 mg	Upsher-Smith Laboratories, Inc., 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 084644	Chlordiazepoxide HCl Capsules USP, 5 mg	Do.
ANDA 084710	Ogen (estropipate) Vaginal Cream USP, 1.5 mg/g	Pfizer Inc.
ANDA 085061	Folic Acid Tablets USP, 1 mg	Contract Pharmacal Corp., c/o SciRegs International Inc.
ANDA 085933	Phentermine HCl Tablets USP	Lemmon Co., 650 Cathill Rd., Sellersville, PA 18960.
ANDA 086494	Chlordiazepoxide HCl Capsules, 25 mg	Teva Pharmaceuticals USA, Inc.
ANDA 086821	Hydroxyzine HCl Injection USP, 50 mg/mL	Hospira, Inc.
ANDA 087416	Hydroxyzine HCl Injection USP, 25 mg/mL, Carpuject	Do.
ANDA 087546	Hydroxyzine HCl Injection USP, 50 mg/mL, Carpuject	Do.
ANDA 087862	Hydroxyzine HCl Tablets USP, 100 mg	Sun Pharmaceutical Industries, Inc.
ANDA 088147	Aminophylline in Sodium Chloride 0.45% Injection, 100 mg/100 mL and 200 mg/100 mL.	Hospira, Inc.
ANDA 088367	Lidocaine HCl Injection USP, 10%	Do.
ANDA 088542	Lidocaine HCl Injection USP, 4%	Do.
ANDA 089162	Cyclopentolate HCl Ophthalmic Solution, 1%	Alcon Pharmaceuticals, Ltd., 6201 South Freeway TC–45, Fort Worth, TX 76134.
ANDA 089347	Diatrizoate Meglumine and Diatrizoate Sodium Injection USP, 66%; 10%.	Bracco Diagnostics Inc., 259 Prospect Plains Rd., Bldg. H, Monroe Township, NJ 08831.
ANDA 089393	Glycopyrrolate Injection USP, 0.2 mg/mL	Hospira, Inc.
ANDA 089488	Diphenhydramine HCl Capsules, 25 mg	Sun Pharmaceutical Industries, Inc.
ANDA 089521	Phenytoin Sodium Injection USP, 50 mg/mL, Ampule	Hospira, Inc.
ANDA 089537	Procainamide HCl Injection USP, 500 mg/mL, Carpuject	Do.
ANDA 089744	Phenytoin Sodium Injection USP, 50 mg/mL, Carpuject	Do.
ANDA 089915	Leucovorin Calcium for Injection, EQ 100 mg base/vial	Pharmachemie B.V., c/o SICOR Pharmaceuticals, Inc., 19 Hughes, Irvine, CA 92618.
NDA 202258	Victrelis (boceprevir) Capsules, 200 mg	Merck Sharp & Dohme Corp., Subsidiary of Merck & Company, Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 203093	Vitekta (elvitegravir) Tablets, 85 mg and 150 mg	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective November 2, 2017. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on the date that this notice becomes effective (see **DATES**) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 27, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21177 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4977]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; 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 or Agency) announces a forthcoming public

advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The public meeting will be held on October 31, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–4977. The docket will close on October 27, 2017. Submit either electronic or written comments on this public meeting by October 27, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 27, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 27, 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.

Comments received on or before October 17, 2017, will be provided to the committees. Comments received after that date will be taken into consideration by the Agency.

You may submit comments as follows:

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, your 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 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.
- 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–4977 for ''Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *kalyani.bhatt@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 *https://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.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss new drug application (NDA) 209819, buprenorphine subcutaneous injection, submitted by Indivior Pharmaceuticals, Inc., for treatment of opioid dependence.

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 *https://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 committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 17, 2017, will be provided to the committees. 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 October 6, 2017. 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 October 10, 2017.

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 disabilities. If you require special accommodations due to a disability, please contact Kalyani Bhatt 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 *https://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).

Dated: September 27, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21170 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0502]

Range of Risk Evaluation and Mitigation Strategies Platform Standards Initiative: Needs Assessment; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is seeking public input on the design of the REMS Platform Standards Initiative, as well as methods and best practices for its construction. To facilitate this, FDA is making available the ''REMS Platform Standards Initiative: Needs Assessment'' (needs assessment), which summarizes a range of risk evaluation and mitigation strategies (REMS) activities that could be standardized and integrated into the health care system through the use of electronic data standards.

DATES: The comment period will be open indefinitely.

ADDRESSES: You may submit comments as follows:

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, your 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 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.
- 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–2013–N–0502 for ''REMS Platform Standards Initiative: Needs Assessment; Request for Comments.'' Received comments 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 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