Page 2 – Ms. Meyer, DiaSorin Incorporated

FDA does not have concerns with the use of any remaining inventory of the LIAISON XL Zika Capture IgM II assay that was distributed prior to revocation of the EUA, when such product is used in conjunction with the LIAISON XL Zika Capture IgM II assay labeling associated with the device cleared on October 28, 2019, under premarket notification submission K192046. FDA encourages the relabeling of any product already manufactured but not distributed prior to the revocation of the EUA with the LIAISON XL Zika Capture IgM II assay labeling associated with the device cleared on October 28, 2019, under premarket notification submission K192046. Importantly, the LIAISON XL Zika Capture IgM II assay product for which FDA had issued an EUA and the device cleared under K192046 are manufactured under the same quality system. DiaSorin should instruct customers who have remaining LIAISON XL Zika Capture IgM II assay EUA product inventory to use their EUA product in combination with labeling associated with the device cleared on October 28, 2019, under premarket notification submission K192046, or to work with DiaSorin to replace the EUA product with the device cleared under K192046. FDA encourages DiaSorin to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the labeling associated with the device cleared on October 28, 2019, under premarket notification submission K192046.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00063 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5843]

Pharmacia and Upjohn Co., et al.; Withdrawal of Approval of 19 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 19 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 7, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 004570	Heparin Sodium Injection, 1,000 units/milliliter (mL), 5,000 units/mL, and 10,000 units/mL.	Pharmacia and Upjohn Co. (a subsidiary of Pfizer Inc.), 235 East 42nd St., New York, NY 10017–7555.
NDA 009838	Reserpine Tablets, 0.1 milligram (mg) and 0.25 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80020–1632.
NDA 017063	Ismotic (isosorbide solution), 100 grams (g)/220 mL	Alcon Research, LLC, 6201 South Freeway, Fort Worth, TX 76134–2099.
NDA 017521	Dextrose Injection, 0.2 g/mL, 0.3 g/mL, 0.4 g/mL, 0.5 g/mL, 0.6 g/mL, and 0.7 g/mL.	Baxter Healthcare Corp., 1 Baxter Parkway, Deerfield, IL 60015.
NDA 017690	Imodium (loperamide hydrochloride (HCl)) Capsules, 2 mg.	Johnson and Johnson Consumer Inc., McNeil Consumer Healthcare Division, 7050 Camp Hill Rd., Fort Washington, PA 19034.
NDA 017694	Imodium (loperaminde HCl) Capsules, 2 mg	Do.

Application No.	Drug	Applicant
NDA 018361	Serophene (clomiphene citrate) Tablets, 50 mg	EMD Serono, Inc., 1 Technology Pl., Rockland, MA 02370.
NDA 020262	Taxol (paclitaxel) Injection, 6 mg/mL	HQ Specialty Pharma Corp., 120 Route 17 North, Paramus, NJ 07652.
NDA 020264	Megace (megestrol acetate) Oral Suspension, 40 mg/mL.	Bristol-Myers Squibb Co., P.O. Box 4000, Mail Stop: D.2341, Princeton, NJ 08543–4000.
NDA 020413	Zerit (stavudine) for Oral Solution, 1 mg/mL	Do.
NDA 020823	Exelon (rivastigmine tartrate) Capsules, equivalent to (EQ) 1.5 mg base, EQ 3 mg base, EQ 4.5 mg base, and EQ 6 mg base.	Novartis Pharmaceuticals Corp.
NDA 021025	Exelon (rivastigmine tartrate) Solution, EQ 2 mg base/mL.	Do.
NDA 021217	Exalgo (hydromorphone HCl) Extended-Release Tablets, 8 mg, 12 mg, 16 mg, and 32 mg.	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119.
NDA 022046	Bupivacaine HCl and epinephrine bitartrate Injection, 0.5%/0.0091 mg/mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
NDA 050632	Azactam (aztreonam) 10 mg/mL, 20 mg/mL, and 40 mg/mL.	Bristol-Myers Squibb Co.
NDA 202342	Esomeprazole Strontium Delayed-Release Capsules, EQ 20 mg base and EQ 40 mg base.	R2 Pharma, LLC, 11550 North Meridian St., Suite 290, Carmel, IN 46032–5505.
NDA 207931	Technivie (ombitasvir, paritaprevir, and ritonavir) Tablets, 12.5 mg/75 mg/50 mg.	AbbVie Inc., 1 North Waukegan Rd., Dept. PA77/Bldg. AP30, North Chicago, IL 60064.
NDA 208603	Arymo ER (morphine sulfate) Extended-Release Tablets, 15 mg, 30 mg, and 60 mg.	Zyla Life Sciences US Inc., 600 Lee Rd., Suite 100, Wayne, PA 19087.
NDA 208624	Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir) Extended-Release Tablets, 200 mg/8.33 mg/50 mg/33.33 mg.	AbbVie Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of February 7, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. 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 February 7, 2020 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: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00075 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6098]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration-Regulated Products)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information for the generic collection for focus groups as used by FDA (all FDA-regulated products).

DATES: Submit either electronic or written comments on the collection of information by March 9, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2020. 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, 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