Application No.	Drug	Applicant
ANDA 078665	Next Choice (levonorgestrel) Tablets, 0.75 mg	Foundation Consumer Healthcare, LLC, 1190 Omega Dr., Pittsburgh, PA 15205.
ANDA 086809	Spironolactone Tablets USP, 25 mg	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.
ANDA 087143	Acetasol HC (hydrocortisone and acetic acid) Otic Solution USP, 1% and 2%.	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 088432	Meperidine HCl Injection USP, 10 mg/mL	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045.
ANDA 090288	Naratriptan Tablets USP, EQ 1 mg base and EQ 2.5 mg base.	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.
ANDA 091597	Gemcitabine for Injection USP, EQ 200 mg base/vial and EQ 1 g base/vial.	Sagent Pharmaceuticals, Inc., 1901 North Roselle Rd., Schaumburg, IL 60195.
ANDA 200670	Next Choice One Dose (levonorgestrel) Tablets, 1.5 mg	Foundation Consumer Healthcare, LLC.
ANDA 203384	Epinastine HCl Ophthalmic Solution, 0.05%	CASI Pharmaceuticals, Inc., c/o Target Health, 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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of February 7, 2020. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table.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. 2020–00076 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–5801]

Revocation of Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of and/or Diagnosis of Zika or Ebola Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of three Emergency Use Authorizations (EUAs) (the Authorizations) issued to OraSure Technologies, Inc. (OraSure) for the OraQuick Ebola Rapid Antigen Test used with whole blood specimens; OraSure for the OraQuick Ebola Rapid Antigen Test used with cadaveric oral fluid swab specimens; and DiaSorin Inc. (DiaSorin) for the LIAISON XL Zika Capture IgM II assay. FDA revoked both of OraSure's Authorizations on October 10, 2019, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in consideration of a De Novo classification request granted to OraSure for the OraQuick Ebola Rapid Antigen Test on October 10, 2019. FDA revoked DiaSorin's Authorization on October 28, 2019, under the FD&C Act, in consideration of the premarket clearance of DiaSorin's LIAISON XL Zika Capture IgM II assay, which FDA determined to be substantially equivalent to a legally marketed class II predicate device on October 28, 2019. The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: OraSure's Authorizations are revoked as of October 10, 2019. DiaSorin's Authorization is revoked as of October 28, 2019.

ADDRESSES: Submit written requests for single copies of the revocation(s) to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

First, on July 31, 2015, FDA issued an EUA to OraSure for the OraQuick Ebola Rapid Antigen Test used with whole blood specimens, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on September 14, 2015 (80 FR 55125), as required by section 564(h)(1) of the FD&C Act. In response to requests from OraSure, this EUA was amended on March 18, 2016, and January 30, 2019.

Second, on March 4, 2016, FDA issued an EUA to OraSure for the OraQuick Ebola Rapid Antigen Test used with cadaveric oral fluid, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on April 22, 2016 (81 FR 23709), as required by section 564(h)(1) of the FD&C Act. In response to requests from OraSure, this EUA was amended on November 14, 2016, and February 1, 2019. Subsequently, on October 10, 2019, FDA granted a De Novo classification request for the OraQuick Ebola Rapid Antigen Test under the generic name ''Device to detect antigens of biothreat microbial agents in human clinical specimens,'' as Class II (special controls) under product code QID (*https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190025.pdf*).

Third, on April 5, 2017, FDA issued an EUA to DiaSorin for the LIAISON XL

Zika Capture IgM II assay, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on June 30, 2017 (82 FR 29886), and corrected on July 10, 2017 (82 FR 31783), as required by section 564(h)(1) of the FD&C Act. In response to requests from DiaSorin, this EUA was amended on November 6, 2017, and December 27, 2018. Subsequently, DiaSorin submitted a premarket notification to FDA for the LIAISON XL Zika Capture IgM II assay. On October 28, 2019, FDA determined that the LIAISON XL Zika Capture IgM II assay was substantially equivalent to a legally marketed class II predicate device under product code QFO with the generic name ''Zika virus serological reagents'' (*https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192046.pdf*).

II. EUA Criteria for Issuance No Longer Met

Under section 564(g)(2) of the FD&C Act, the Secretary of HHS may revoke an EUA if, among other things, the criteria for issuance are no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. On October 10, 2019, FDA revoked the EUAs for OraSure's OraQuick Ebola Rapid Antigen Test for use with whole blood specimens and cadaveric oral fluid, and on October 28, 2019, FDA revoked the EUA for DiaSorin's LIAISON XL Zika Capture IgM II assay because the criteria for issuance were no longer met. FDA determined that the criteria for issuance of OraSure's two Authorizations are no longer met because OraSure had a De Novo classification request granted for the OraQuick Ebola Rapid Antigen Test as a Class II device under the generic name ''Device to detect antigens of biothreat microbial agents in human clinical specimens'' on October 10, 2019.

FDA also determined that the criteria for issuance of DiaSorin's Authorization are no longer met because the LIAISON XL Zika Capture IgM II assay was determined to be substantially equivalent to a legally marketed class II predicate device with the generic name ''Zika virus serological reagents.'' As such, in each case FDA concluded that there is an adequate, approved, and available alternative for purposes of section 564(c)(3) of the FD&C Act and accordingly revoked the Authorizations pursuant to section 564(g)(2)(B) of the Act.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at *https://www.regulations.gov/*.

IV. The Revocations

Having concluded that the criteria for revocations of the Authorizations under section 564(g) of the FD&C Act are met, FDA has revoked the EUAs for OraSure's OraQuick Ebola Rapid Antigen Test for use with whole blood specimens and cadaveric oral fluid and for DiaSorin's LIAISON XL Zika Capture IgM II assay. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–22–P

U.S. FOOD & DRUG ADMINISTRATION

October 10, 2019

Tiffany Miller
Director, Regulatory Affairs
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Dear Ms. Miller:

This letter is to notify you of the revocation of the Emergency Use Authorizations (EUA150006 and EUA160001) for emergency use of OraSure Technologies Inc.'s ("OraSure's"): (1) OraQuick Ebola Rapid Antigen Test for use with whole blood specimens issued on July 31, 2015, and amended on March 18, 2016, and January 30, 2019 (EUA150006), and (2) OraQuick Ebola Rapid Antigen Test for use with cadaveric oral fluid issued on March 4, 2016, and amended on November 14, 2016, and February 1, 2019 (EUA160001).

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the circumstances described under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorizations under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. The OraSure OraQuick Ebola Rapid Antigen Test had a De Novo classification request granted as a Class II device under the generic name "Device to detect antigens of biothreat microbial agents in human clinical specimens" in 21 CFR 866.4002 on October 10, 2019 (https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190025.pdf). FDA has concluded that this is an adequate, approved[1], and available alternative to OraSure's EUA products (EUA150006 and EUA160001) for diagnosing Ebola Virus Disease.

Accordingly, FDA revokes EUA150006 and EUA160001 for emergency use of both OraQuick Ebola Rapid Antigen Tests, pursuant to section 564(g)(2) of the Act. As of the date of this letter,

[1] As used in section 564(c)(3) of the Act, the term "approved" refers to a product that is approved, authorized, licensed, or cleared under section 505, 510(k), 513, or 515 of the Act or section 351 of the Public Health Service Act.

the OraQuick Ebola Rapid Antigen Tests that were authorized by FDA for emergency use under EUA150006 and EUA160001 are no longer authorized by FDA.

FDA does not have concerns with the use of any remaining inventory of the OraQuick Ebola Rapid Antigen Tests that were distributed prior to revocation of their EUAs, when such product is used in conjunction with the OraQuick Ebola Rapid Antigen Test labeling associated with the De Novo request granted October 10, 2019. FDA encourages the relabeling of any product already manufactured but not distributed prior to the revocation of the EUAs with the OraQuick Ebola Rapid Antigen Test labeling associated with the De Novo request granted October 10, 2019. Importantly, the OraQuick Ebola Rapid Antigen Test products for which FDA had issued EUAs and the product for which FDA has granted De Novo classification are manufactured under the same quality system according to equivalent specifications and lot release criteria. OraSure should instruct customers who have remaining OraQuick Ebola Rapid Antigen Test EUA product inventory to use their EUA product in combination with labeling associated with the De Novo request granted October 10, 2019, or to work with OraSure to replace the EUA product with the device associated with the De Novo request granted October 10, 2019. FDA encourages OraSure to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocations and provide access to the labeling associated with the De Novo request granted October 10, 2019.

Notice of both revocations 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

U.S. FOOD & DRUG ADMINISTRATION

October 28, 2019

Mari Meyer
Vice President, Regulatory and Clinical Affairs,
North America
DiaSorin Incorporated
1951 Northwestern Avenue
Stillwater, MN 55082

Dear Ms. Meyer:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA170003) for emergency use of DiaSorin Inc.'s ("DiaSorin's") LIAISON XL Zika Capture IgM II assay issued on April 5, 2017, and amended on November 6, 2017, and December 27, 2018.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the circumstances described under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. DiaSorin submitted a premarket submission to FDA for the LIAISON XL Zika Capture IgM II (K192046) that was determined to be substantially equivalent to a legally marketed Class II predicate device, classified under 21 CFR 866.3935, with the generic name "Zika virus serological reagents," on October 28, 2019. FDA has concluded that this is an adequate, approved[1], and available alternative to DiaSorin's EUA product (EUA170003) for diagnosing Zika virus infection.

Accordingly, FDA revokes EUA170003 for emergency use of the LIAISON XL Zika Capture IgM II assay, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the LIAISON XL Zika Capture IgM II assay that was authorized by FDA for emergency use under EUA170003 is no longer authorized by FDA.

[1] As used in section 564(c)(3) of the Act, the term "approved" refers to a product that is approved, authorized, licensed, or cleared under section 505, 510(k), 513, or 515 of the Act or section 351 of the Public Health Service Act.

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.