TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Animal Feed Regulatory Program in the United States	34	1	34	569	19,346

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to the information collection are State agencies seeking to avail themselves of the options described in the document. State agencies that conduct feed inspections under contract are interested in implementing the standards. The total estimated annual recordkeeping burden for implementation is 569 hours per respondent. The burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 11 standards contained in the AFRPS. The hours per State feed regulatory program will average the same to account for continual improvement and self-sufficiency in the program. Our burden estimate reflects a decrease of 100,654 hours as a result of fewer respondents to the collection and a reevaluation of the time we ascribe for recordkeeping activities.

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00073 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–5550]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 abbreviated new drug applications (ANDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 7, 2020.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: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

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 described 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
ANDA 040448	Phentermine Hydrochloride (HCl) Capsules USP, 30 milligrams (mg).	Elite Laboratories, Inc., 165 Ludlow Ave., Northvale, NJ 07647.
ANDA 060272	E-Mycin (erythromycin) Delayed-Release Tablets USP, 250 mg and 333 mg.	Arbor Pharmaceuticals, LLC, 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.
ANDA 061639	E.E.S. 200 (erythromycin ethylsuccinate) for Oral Suspension, Equivalent to (EQ) 200 mg base/5 milliliters (mL).E.E.S. 400 (erythromycin ethylsuccinate) for Oral Suspension, EQ 400 mg base/5 mL.	Do.
ANDA 062290	EryDerm (erythromycin) Topical Solution USP, 2%	Arbor Pharmaceuticals, LLC.
ANDA 062304	Pediamycin (erythromycin ethylsuccinate) Oral Suspension USP, EQ 200 mg base/5 mL Pediamycin 400 (erythromycin ethylsuccinate) Oral Suspension USP, EQ 400 mg base/5 mL.	Do.
ANDA 062659	Claforan ADD-Vantage (cefotaxime) for Injection USP, EQ 1 gram (g) base/vial and EQ 2 g base/vial.	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
ANDA 070347	Hydro-Ride (amiloride HCl and hydrochlorothiazide) Tablets, EQ 5 mg Anhydrous/50 mg.	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 071142	Clonidine HCl and Chlorthalidone Tablets USP, 0.3 mg/15 mg.	Do.
ANDA 071178	Clonidine HCl and Chlorthalidone Tablets USP, 0.2 mg/15 mg.	Do.
ANDA 071179	Clonidine HCl and Chlorthalidone Tablets USP, 0.1 mg/15 mg.	Do.
ANDA 073191	Triamterene and Hydrochlorothiazide Capsules USP, 50 mg/25 mg.	CASI Pharmaceuticals, Inc., c/o Target Health, Inc., 261 Madison Ave., 24th Floor, New York, NY 10016.
ANDA 073416	E–Z Scrub (chlorhexidine gluconate) Sponge, 4%	Becton, Dickinson and Co., 9450 South State St., Sandy, UT 84070.
ANDA 076075	Econazole Nitrate Cream, 1%	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.
ANDA 076192	Ribavirin Capsules USP, 200 mg	Do.
ANDA 076514	Midodrine HCl Tablets USP, 2.5 mg, 5 mg, and 10 mg	Do.

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