[FR Doc. 2021–25103 Filed 11–17–21; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1195]

Discovery Therapeutics, LLC, et al.; Withdrawal of Approval of 18 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 18 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of December 20, 2021.

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 040619	Methimazole Tablets, 15 milligrams (mg)	Discovery Therapeutics, LLC, 2831 Deer Hound Way, Palm Harbor, FL 34683.
ANDA 070254	Naloxone Hydrochloride (HCl) Injection, 0.4 mg/milliliters (mL).	Hospira, Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045.
ANDA 070586	Bupivacaine HCl Injection, 0.25%	Do.
ANDA 071850	Morphine Sulfate Injection, 1 mg/mL	Do.
ANDA 075220	Desmopressin Acetate Injection, 0.004 mg/mL	Do.
ANDA 076498	Tretinoin Cream, 0.05%	ZO Skin Health, Inc., 9685 Research Dr., Irvine, CA 92618.
ANDA 077245	Ciprofloxacin Injection, 200 mg/20 mL (10 mg/mL) and 400 mg/40 mL (10 mg/mL).	Hospira, Inc.
ANDA 080409	Lidocaine HCl Solution, 4%	Do.
ANDA 087446	Chloroprocaine HCl Injection, 3%	Do.
ANDA 087447	Chloroprocaine HCl Injection, 2%	Do.
ANDA 201653	Levocetirizine Dihydrochloride Tablets, 5 mg	Sun Pharmaceutical Industries, Inc., U.S. Agent for Sun Pharmaceutical Industries Ltd., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 202524	Levetiracetam Extended Release Tablets, 500 mg and 750 mg.	Rouses Point Pharmaceuticals, LLC, 11 Commerce Dr., Cranford, NJ 07016.
ANDA 202857	Daptomycin Powder for Injection, 500 mg/vial	Hospira, Inc.
ANDA 203885	Amiodarone HCl Injection, 50 mg/mL	Do.
ANDA 207864	Eptifibatide Injection, 2 mg/mL and 75 mg/100 mL	The WhiteOak Group, LLC, U.S. Agent for Hybio Pharmaceutical Co., Ltd., 1629 K St. NW, Suite 300, Washington, DC 20006.
ANDA 209489	Caspofungin Acetate Powder for Injection, 50 mg/vial and 70 mg/vial.	Cipla USA, Inc., U.S. Agent for Cipla Limited, 10 Independence Blvd., Suite 300, Warren, NJ 07059.
ANDA 210283	Clofarabine Injection, 20 mg/20 mL (1 mg/mL)	Hospira, Inc.
ANDA 210855	Sodium Nitroprusside Injection, 25 mg/mL	Cipla USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 20, 2021. 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 December 20, 2021 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: November 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25111 Filed 11–17–21; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NICHD.

Date: December 3, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: A report by the Acting Scientific Director, NICHD, on the status of the NICHD

Division of Intramural Research; current organizational structure; to review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 31 Center Drive, Bethesda, MD 20892, (Video-Assisted Meeting).

Contact Person: Chris J. McBain, Ph.D., Acting Scientific Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 10 Center Drive, Room 10D39, Bethesda, MD 20892, (301) 594–5984, *mcbainc@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory/bsc,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: November 15, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25161 Filed 11–17–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0139]

Electronic Visa Update System (EVUS)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; revision of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than January 18, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0139 in the subject line and the agency name. Please use the following method to submit comments:

Email: Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/*.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Electronic Visa Update System (EVUS).

OMB Number: 1651–0139.

Form Number: N/A.

Current Actions: Revision of an existing information collection.

Type of Review: Revision.

Affected Public: Individuals.

Abstract: DHS developed the Electronic Visa Update System (EVUS) to assure robust screening of foreign nationals prior to travel to the United States. EVUS provides for robust traveler screening and verification to better identify foreign nationals who may be inadmissible to the United States. This results in enhanced national security, improved public safety, and a reduced number of delays upon arrival in the United States, all while facilitating legitimate travel.

Initially, the program is limited to nonimmigrant aliens presenting passports issued by the People's Republic of China (PRC) containing unrestricted, maximum validity B–1 (business visitor), B–2 (visitor for pleasure), or combination B–1/B–2 visas, generally valid for 10 years. PRC membership in EVUS became possible on November 12, 2014, when, in a reciprocal agreement, the U.S. Department of State expanded the validity of U.S. visitor visas issued to PRC nationals from one to ten years.

To ensure compliance with the Visa Waiver Program Improvement and Terrorist Travel Prevention Act of 2015, Public Law 114–113, 129 Stat. 2242, CBP will continuously update the application question with the list of nationals ineligible from traveling to the United States, as designated in accordance with section 217(a)(12) of the Immigration and Nationality Act, as amended (8 U.S.C. 1187(a)(12)).

Recent Changes

On May 31, 2019, the Department of State updated its immigrant and nonimmigrant visa application forms to request additional information, specifically social media identifiers, from most U.S. visa applicants worldwide. As a result, DHS is changing the EVUS application social media data field from optional to mandatory. National security is the top priority when adjudicating EVUS applications, and every prospective traveler to the United States undergoes extensive security screening. CBP is continually working to find mechanisms to improve our screening processes to protect U.S. visitors while supporting legitimate travel to the United States. DHS already requests information on contacts, travel history, and family members from all EVUS applicants. Changing the social medial field to mandatory in the EVUS application will enhance our vetting capabilities and assist in confirming applicants' identities. While the field is