

### III. Public Meeting Information

#### A. Purpose and Scope of the Meeting

The meeting format will include presentations by FDA and a series of panels representing different stakeholder groups. We will also provide an opportunity for other stakeholders to provide public comment at the meeting. FDA policy issues outside of the BsUFA program are beyond the scope of these reauthorization discussions. Accordingly, the comments should focus on process enhancements and funding issues, and not on policy issues.

#### B. Participating in the Public Meeting

**Registration:** Persons interested in attending this virtual public meeting should register online by 11:59 p.m. Eastern Time on November 5, 2020, at <https://bsufaiii-publicmeeting.eventbrite.com>. Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone.

**Opportunity for Public Comment:** Those who register online by November 5, 2020, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by November 5, 2020, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the

approximate time each comment is to begin, and will select and notify participants by November 12, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

**Streaming Webcast of the Public Meeting:** The webcast for this public meeting is available at <https://collaboration.fda.gov/bsufanov2020/>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/industry/biosimilar-user-fee-amendments/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-11192020-11192020>.

Dated: October 26, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-24028 Filed 10-29-20; 8:45 am]

**BILLING CODE 4164-01-P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2020-N-2088]

#### Sanofi-Aventis U.S. LLC, et.al.; Withdrawal of Approval of 11 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 11 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 November 30, 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](mailto: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 061884 .....	Rifamate (isoniazid and rifampin) Capsules, 150 milligrams (mg); 300 mg.	Sanofi-Aventis U.S. LLC 55 Corporate Dr., Bridgewater, NJ 08807.
ANDA 065196 .....	Ceftazidime for Injection, 1 gram(g)/vial .....	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053.
ANDA 065197 .....	Cefotaxime for Injection, Equivalent to (EQ) 1 g base/vial; EQ 2 g base/vial; EQ 500 mg base/vial.	Do.
ANDA 078229 .....	Terbinafine Hydrochloride (HCl) Tablets, EQ 250 mg base.	Do.
ANDA 081134 .....	Niacin Tablets, 500 mg .....	Do.
ANDA 091659 .....	Heparin Sodium Injection, 5,000 units/milliliter (mL) .....	CASI Pharmaceuticals, Inc., 9620 Medical Center Dr., Suite 300, Rockville, MD 20850.
ANDA 202647 .....	Granisetron HCl Injection, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL).	Yung Shin Pharmaceutical Industrial Co., Ltd./Carlsbad Technology, Inc., 5922 Farnsworth Ct., Carlsbad, CA 92008.
ANDA 202648 .....	Granisetron HCl Injection, EQ 1 mg base/mL (EQ 1 mg base/mL); EQ 4 mg base/4 mL (EQ 1 mg base/mL).	Do.
ANDA 205173 .....	Bosentan Tablets, 62.5 mg and 125 mg .....	Mylan Pharmaceuticals Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 207843 .....	Telmisartan Tablets, 20 mg, 40 mg, and 80 mg .....	Hisun Pharmaceutical (Hangzhou) Co., Ltd./Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.

Application No.	Drug	Applicant
ANDA 210681 .....	Ranitidine HCl Capsules, EQ 150 mg base and EQ 300 mg base.	Novitium Pharma LLC, 70 Lake Dr., East Windsor, NJ 08520.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 30, 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 November 30, 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: October 26, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-24012 Filed 10-29-20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Radiation Exposure Screening and Education Program, OMB No. 0906-0012—Extension

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to

submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than December 29, 2020.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Radiation Exposure Screening and Education Program, OMB No. 0906-0012—Extension.

*Abstract:* The Radiation Exposure Screening and Education Program (RESEP) is authorized by section 417C of the Public Health Service Act (42 U.S.C. 285a-9). The purpose of RESEP is to assist individuals who live (or lived) in areas where U.S. nuclear weapons testing occurred and who are diagnosed with cancer and other radiogenic diseases caused by exposure to nuclear fallout or nuclear materials such as uranium. RESEP funds support eligible health care organizations in: Implementing cancer screening programs; developing education programs; disseminating information on radiogenic diseases and the importance of early detection; screening eligible individuals for cancer and other

radiogenic diseases; providing appropriate referrals for medical treatment; and facilitating documentation of Radiation Exposure.

*Need and Proposed Use of the Information:* For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993 (Pub. L. 103-62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy, including: (a) Demographics for the RESEP program user population; (b) medical screening activities for cancers and other radiogenic diseases; (c) exposure and presentation types for eligible radiogenic malignant and nonmalignant diseases; (d) referrals for appropriate medical treatment; (e) eligibility counseling and referral assistance for the RECA; and (f) program outreach and education activities. These measures will speak to the Office's progress toward meeting the goals set.

*Likely Respondents:* Radiation Exposure Screening and Education Program award recipients.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to: Review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Radiation Exposure Screening and Education Program .....	8	1	8	12	96
	8	.....	8	.....	96