

| 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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 30, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table.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]

**BILLING CODE 4164–01–P**

**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* 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* 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 Expose Screening and Education Program ..... | 8                     | 1                                  | 8               | 12                                     | 96                 |
|  | 8                     | .....                              | 8               | .....                                  | 96                 |

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2020-24122 Filed 10-29-20; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Ninth Meeting of the National Clinical Care Commission

**AGENCY:** Office on Women's Health, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The National Clinical Care Commission (the Commission) will conduct its ninth meeting virtually on November 17, 2020. The Commission is charged to evaluate and make recommendations to the U.S. Department of Health and Human Services (HHS) Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to diabetes and its complications.

**DATES:** The meeting will take place on November 17, 2020, from 1 p.m. to approximately 5:30 p.m. Eastern Standard time (EST).

**ADDRESSES:** The meeting will be held online via webinar. To register to attend the meeting, please visit the registration website at [https://kauffmaninc.adobeconnect.com/nccc\\_9/event/event\\_info.html](https://kauffmaninc.adobeconnect.com/nccc_9/event/event_info.html).

**FOR FURTHER INFORMATION CONTACT:** Clydette Powell, M.D., M.P.H., F.A.A.P., Designated Federal Officer, National Clinical Care Commission, U.S. Department of Health and Human Services, Office on Women's Health, 200 Independence Ave. SW 7th Floor, Washington DC 20201. Phone: (240) 453-8239. Email: [OHQ@hhs.gov](mailto:OHQ@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The National Clinical Care Commission Act (Pub. L. 115-80) requires the HHS Secretary to establish the National Clinical Care Commission. The Commission consists of representatives

of specific federal agencies and non-federal individuals who represent diverse disciplines and views. The Commission will evaluate and make recommendations to the HHS Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to diabetes and its complications.

The ninth meeting will be held virtually and will consist of updates from the Commission's three subcommittees and a discussion of public comments and outreach to stakeholder organizations. Additionally, the Commission will discuss the second round of potential "action plans" from the subcommittees (*i.e.*, recommendations). The final meeting agenda will be available prior to the meeting at <https://health.gov/our-work/health-care-quality/national-clinical-care-commission/meetings>.

**Public Participation at Meeting:** The Commission invites public comment on issues related to the Commission's charge. There will be an opportunity for limited oral comments (each no more than 3 minutes in length) at this virtual meeting. Virtual attendees who plan to provide oral comments at the Commission meeting during a designated time must register prior to the meeting at [https://kauffmaninc.adobeconnect.com/nccc\\_9/event/event\\_info.html](https://kauffmaninc.adobeconnect.com/nccc_9/event/event_info.html).

Written comments are welcome throughout the entire development process of the Commission's work and may be emailed to [OHQ@hhs.gov](mailto:OHQ@hhs.gov). Written comments should not exceed three pages in length.

Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying Jennifer Gillissen at [jennifer.gillissen@kauffmaninc.com](mailto:jennifer.gillissen@kauffmaninc.com) by November 9, 2020.

**Authority:** The National Clinical Care Commission is required under the National Clinical Care Commission Act (Pub. L. 115-80). The Commission is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C., App.) which sets forth standards for the formation and use of federal advisory committees.

Dated: October 27, 2020.

**Dorothy Fink,**

*Deputy Assistant Secretary for Women's Health, Office of the Assistant Secretary for Health.*

[FR Doc. 2020-24126 Filed 10-29-20; 8:45 am]

**BILLING CODE 4150-32-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Small Business Innovation Research (SBIR) Phase II Program Contract Solicitation (PHS 2019-1) Topic 74.

**Date:** November 24, 2020.

**Time:** 10:00 a.m. to 1:00 p.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G62A, Rockville, MD 20892, Bethesda, MD (Virtual Meeting).

**Contact Person:** Eleazar Cohen, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G62A, Bethesda, MD 20892, (240) 669-5081, [ecohen@niaid.nih.gov](mailto:ecohen@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 26, 2020.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-24081 Filed 10-29-20; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Final NIH Policy for Data Management and Sharing and Supplemental Information

**AGENCY:** National Institutes of Health, HHS.