

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online at https://fda.zoomgov.com/webinar/register/WN_DBPaDGi5QXaaCoxk/kx7g no later than December 5, 2022. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Also, please self-identify as a member of one of the following stakeholder categories: scientific or academic experts, veterinary professionals, patients and consumer advocacy groups, or the regulated industry, and whether you are requesting a scheduled presentation.

Early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

If you need special accommodations due to a disability, please contact Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) no later than December 1, 2022.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session and 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 presentations, and request time for a joint presentation, or submit requests for designated representatives to participate.

We will determine the amount of time allotted to each presenter and the

approximate time each oral presentation is to begin, and we will notify participants by December 5, 2022. All requests to make oral presentations must be received by December 1, 2022, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) no later than December 5, 2022. No commercial or promotional material will be permitted to be presented at the public meeting.

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/animal-drug-user-fee-act-adufa/adufa-meetings>.

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-25274 Filed 11-18-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2826]

Allergan Sales, LLC, et al.; Withdrawal of Approval of 10 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 10 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 21, 2022.

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 040099	Norco (hydrocodone bitartrate and acetaminophen) Tablets, 5 milligrams (mg)/325 mg.	Allergan Sales, LLC, U.S. Agent for Allergan Pharmaceuticals International Limited, 5 Giralda Farms, Madison, NJ 07940.
ANDA 040148	Norco (hydrocodone bitartrate and acetaminophen) Tablets, 2.5 mg/325 mg, 5 mg/325 mg, 7.5 mg/325 mg, 10 mg/325 mg, and 10 mg/500 mg.	Do.
ANDA 076434	Chlorhexidine Gluconate Solution, 0.12%	Sunstar Americas, Inc., 301 East Central Rd., Schaumburg, IL 60195.
ANDA 079076	Ranitidine Hydrochloride (HCl) Injection, Equivalent to (EQ) 25 mg base/milliliters (mL).	Mylan Pharmaceuticals Inc., a Viatris Company, U.S. Agent for Mylan Laboratories Limited, 3711 Collins Ferry Rd., Morgantown, WV 26505.
ANDA 090054	Ranitidine HCl Syrup, EQ 15 mg base/mL	Tolmar Inc., 701 Centre Ave., Fort Collins, CO 80526.
ANDA 201804	Letrozole Tablets, 2.5 mg	Indicus Pharma, LLC, 2530 Meridian Parkway, Durham, NC 27713.
ANDA 201832	Nimodipine Capsules, 30 mg	Sofgen Pharmaceuticals, LLC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180.
ANDA 203419	Donepezil HCl Tablets, 23 mg	Indicus Pharma, LLC.
ANDA 203519	Morphine Sulfate Solution, 20 mg/5 mL	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.
ANDA 206151	Abacavir Sulfate and Lamivudine Tablets, EQ 600 mg base; 300 mg.	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Limited, 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 21, 2022. 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 21, 2022 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 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-25315 Filed 11-18-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Input on the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans: Request for Information

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This Request for information (RFI) invites comments and suggestions on the *National Strategy for the Prevention and Control of Vector-Borne Diseases*. The *Strategy* represents the Federal Government's priorities for addressing vector-borne disease (VBD) threats.

DATES: To be assured consideration, comments must be received via the method provided below, no later than midnight Eastern Time (ET) on December 21, 2022. Submissions received after the deadline will not be reviewed.

ADDRESSES: Comments, including mass comment submissions, must be submitted electronically at <http://www.regulations.gov>. Search for this RFI by typing a keyword in the search field on the homepage. Click on the "Comment Now" button on RFI and you can submit your comments including attachments in a window titled, "Your Information." For help finding this RFI

and/or submitting comments, please visit <https://www.regulations.gov/help>.

FOR FURTHER INFORMATION CONTACT: Dr. Kristen Honey, Chief Data Scientist and Executive Director of InnovationX, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, vectorbornedisease@hhs.gov, (202) 853-7680.

SUPPLEMENTARY INFORMATION: It is important to read this entire RFI notice to ensure an adequate response is prepared and to have a full understanding of how your response will be acknowledged and used. **Inspection of Public Comments:** All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

The Federal Government is developing a national strategy for the prevention and control of vector-borne diseases (VBD) in humans.

The Federal Government has identified 5 goals and 19 strategic priorities which were developed using the framework of the previously released National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans:

- *Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs).*

- *Strategic Priority 1:* Better understand vectors, the pathogens they transmit, and the potential effects of a changing climate.

- *Strategic Priority 2:* Modernize and maintain surveillance systems for vectors, reservoirs, and VBDs.

- *Strategic Priority 3:* Better understand the risk factors for and effects of VBDs on humans.

- *Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases.*

- *Strategic Priority 1:* Identify and characterize novel VBD pathogens and their clinical manifestations.

- *Strategic Priority 2:* Develop, evaluate, and improve diagnostic tests for VBDs.

- *Strategic Priority 3:* Develop and evaluate evidence-based recommendations and guidelines on VBD diagnosis in humans.

- *Strategic Priority 4:* Develop, maintain, and distribute non-commercial diagnostic resources to facilitate VBD testing.

- *Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases.*

- *Strategic Priority 1:* Develop, evaluate, and improve safe and effective VBD prevention tools such as vaccines, vector control strategies, and health communication tools and products that are tailored for communities that are disproportionately affected.

- *Strategic Priority 2:* Develop and evaluate data-driven and adaptive predictive models and decision support tools for VBDs.

- *Strategic Priority 3:* Develop and evaluate evidence-based recommendations and guidelines on VBD prevention.

- *Strategic Priority 4:* Develop and evaluate tools and processes for responding to public health emergencies.

- *Goal 4: Develop and assess drugs and treatment strategies for VBDs.*

- *Strategic Priority 1:* Identify, develop, and evaluate safe and effective drugs and treatment strategies (regimens) for VBDs.

- *Strategic Priority 2:* Develop evidence-based recommendations and guidelines on the treatment and management of VBDs.

- *Strategic Priority 3:* Evaluate drug and treatment use patterns.

- *Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats.*

- *Strategic Priority 1:* Disseminate evidence-based information about VBD prevention and control, guidelines, and recommendations to partners and the public.

- *Strategic Priority 2:* Ensure current and future capacity to implement and adequately and equitably scale safe, effective, and publicly accepted VBD prevention and control programs.

- *Strategic Priority 3:* Monitor and evaluate evidence-based public health programs and tools.

- *Strategic Priority 4:* Respond to public health emergencies resulting from VBD threats.

- *Strategic Priority 5:* Clarify, facilitate, and improve processes to bring regulated diagnostic tests, treatment strategies, vaccines, and vector control products to market.