www.regulations.gov. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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*3. Cheung, Y.T.D., X. Weng, M.P. Wang, et al., ''Effect of Prepaid and Promised Financial Incentive on Follow-Up Survey Response in Cigarette Smokers: A Randomized Controlled Trial,'' *BMC Medical Research Methodology,* vol. 19, Article 138, 2019. (*https://link.springer.com/article/10.1186/s12874-019-0786-9*)

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*7. Yu, S., H.E. Alper, A.M. Nguyen, et al., ''The Effectiveness of a Monetary Incentive Offer on Survey Response Rates and Response Completeness in a Longitudinal Study,'' *BMC Medical Research Methodology,* vol. 17, Article 77, 2017. (*https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-017-0353-1*)

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27652 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5323]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 17, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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 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 under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 021455	Boniva (ibandronate sodium) Tablets, equivalent to (EQ) 2.5 milligrams (mg) base and EQ 150 mg base.	Hoffmann-La Roche, Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080–4990.
NDA 022424	Flowtuss (guaifenesin 200 mg/5 milliliters (mL) and hydrocodone bitartrate 2.5 mg/5 mL) Oral Solution.	Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 17, 2024. 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 listed in the table without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on January 17, 2024 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: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27661 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3740]

Priority Zoonotic Animal Drug Designation and Review Process; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #283 entitled ''Priority Zoonotic Animal Drug Designation and Review Process.'' This draft guidance is intended to assist sponsors pursuing priority zoonotic animal drug (PZAD) designation for a new animal drug. This draft guidance is intended to provide the eligibility criteria for PZAD designation, the process for requesting PZAD designation, and enhancements in the FDA review process for PZADs.

DATES: Submit either electronic or written comments on the draft guidance by February 16, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows: