UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Date: October 28, 2020

BALLOT VOTE SHEET

TO : The Commission
Alberta E. Mills, Secretary

THROUGH: Mary T. Boyle, Executive Director
John G. Mullan, General Counsel

FROM : Mary A. House, Acting Assistant General Counsel

SUBJECT : Petition Requesting Exemption from Special Packaging Requirements of the Poison Prevention Packaging Act for XOFLUZA™ (Baloxavir marboxil)

BALLOT VOTE DUE: Tuesday, November 3, 2020

Genentech, Inc. (Genentech), through counsel, submitted a petition requesting that the Commission exempt the prescription drug, XOFLUZA™ (Baloxavir marboxil), from the special packaging requirements of the Poison Prevention Packaging Act (PPPA). The Office of the General Counsel (OGC) docketed Genentech's request as petition PP 20-1.

In accordance with prior practice, OGC has drafted the attached notice for publication in the *Federal Register,* inviting comments on the petition for a period of 60 days, should the Commission, in its discretion, decide to request comments on the petition. Staff recommends that the Commission NOT issue the draft notice. Staff's recommendation is consistent with agency past practice regarding petitions for exemption from special packaging requirements, where all available information necessary for making the staff's technical decision under the PPPA is provided with the petition. Based on the information provided with the petition, CPSC staff concludes that publication in the *Federal Register* is not necessary.

Please indicate your vote on the following options:

I. Approve publication of the attached document in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

II. Approve publication of the attached document in the *Federal Register*, with changes. (Please specify.)

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(Signature) (Date)

III. Do not approve publication of the attached document in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

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_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice: Petition Requesting Exemption from Special Packaging Requirements of the Poison Prevention Packaging Act for XOFLUZA™ (Baloxavir marboxil)

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC-2020-XXXX]

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission (CPSC) received a petition requesting an exemption from the special packaging requirements of the Poison Prevention Packaging Act (PPPA) for the prescription drug XOFLUZA™ (Baloxavir marboxil). The Commission invites written comments concerning the petition.

DATES: Written comments on the petition must be received by [insert date 60 days after publication in the **Federal Register**].

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2020-XXXX, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: https://www.regulations.gov. Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (e-mail), except through https://www.regulations.gov. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Written Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7479.

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments received without change, including any personal identifiers, contact information, or other personal information provided, to: https://www.regulations.gov. Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for written submissions.

Docket: For access to the docket to read background documents or comments received, go to: https://www.regulations.gov, and insert the docket number, CPSC-2020-XXXX, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Adrienne Layton, Ph.D., Directorate for Health Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville MD 20850; telephone (301) 987-2590; alayton@cpsc.gov.

SUPPLEMENTARY INFORMATION: Genentech, Inc. ("Genentech") requests that the Commission issue an exemption from special packaging requirements of the PPPA for Genentech's prescription drug XOFLUZA™ (Baloxavir marboxil). Commission regulations under the PPPA require special packaging, sometimes called "child-resistant packaging," for prescription drugs in a dosage form intended for oral administration. 16 CFR 1700.14(a)(10). XOFLUZA is currently packaged in compliance with PPPA requirements.

The U.S. Food and Drug Administration (FDA) approved XOFLUZA as a one-dose oral antiviral medication indicated for treatment of influenza (flu) for patients 12 years and older, who have had flu symptoms for no more than 48 hours. XOFLUZA is available in tablet form in two strengths – 40 mg (two tablets of 20 mg each) and 80 mg (two tablets of 40 mg) –

administered based on body weight. Patients are directed to take a single dose. Genentech's petition states that special packaging for XOFLUZA is not required to protect children from serious illness from ingesting XOFLUZA, and that special packaging is not technically feasible, practicable, or appropriate for XOFLUZA.

Interested parties may obtain a copy of the petition by writing or calling the Division of the Secretariat, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7479; email: amills@cpsc.gov.

Dated:

Alberta E. Mills
Secretariat
Consumer Product Safety Commission