: 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2246]

Withdrawal of FDA Notice Regarding Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services is issuing this Notice to withdraw FDA's December 29, 2020 **Federal Register** Notice entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021* because FDA lacked the delegated authority to issue the Notice. The Department is further informing the public that FDA has been ordered to cease further collection efforts related to the Over-the-Counter Drug Monograph User Fee Program until further action is announced in the **Federal Register**.

DATES: The Notice, published in the Federal Register on December 29, 2020 (85 FR 85646), is withdrawn as of (INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER).

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402 4585.

SUPPLEMENTARY INFORMATION:

On December 29, 2020, FDA published a Notice in the **Federal Register** entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021*. 85 FR 85646. The Notice purports to implement certain user fee provisions contained in the in the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Pub. L. No. 116-136, 134 Stat. 281 (March 27, 2020). The Notice was issued without approval of the Secretary. For this

reason, the Notice, Docket No. FDA-2020-N-2246, as published in the **Federal Register** on December 29, 2020, (85 FR 85646), is hereby withdrawn.

FDA has also been ordered to cease collections activities related to the Over-the-Counter Monograph User Fee Program ("OMUFA") until, with the approval of the Secretary, the Department issues further direction concerning FDA's administration of OMUFA which provides the public with notice and opportunity for comment.

Dated: December 31, 2020.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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