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FEDERAL TRADE COMMISSION

16 CFR Part 310

RIN 3084–AA98

Telemarketing Sales Rule Fees

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''Commission'') is amending its Telemarketing Sales Rule (''TSR'') by updating the fees charged to entities accessing the National Do Not Call Registry (''Registry'') as required by the Do-Not-Call Registry Fee Extension Act of 2007.

DATES: This rule is effective October 1, 2024.

ADDRESSES: Copies of this document are available on the internet at the Commission's website: *https://www.ftc.gov.*

FOR FURTHER INFORMATION CONTACT: Ami Joy Dziekan, (202) 326–2648, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: To comply with the Do-Not-Call Registry Fee Extension Act of 2007 (Pub. L. 110–188, 122 Stat. 635, codified at 15 U.S.C. 6152) (''Act''), the Commission is amending the TSR, which is contained in 16 CFR part 310, by updating the fees entities are charged for accessing the Registry. Specifically, the revised rule increases (1) the annual fee for access to the Registry for each area code of data from $78 to $80 per area code, and (2) the maximum amount that will be charged to any single entity for accessing area codes of data from $21,402 to $22,038. Entities may add area codes during the second six months of their annual subscription period, and the fee for those additional area codes increases from $39 to $40.

These increases are in accordance with the Act, which specifies that beginning after fiscal year 2009, the dollar amounts charged shall be increased by an amount equal to the amounts specified in the Act, multiplied by the percentage (if any) by which the average of the monthly consumer price index (for all urban consumers published by the Department of Labor) (''CPI'') for the most recently ended 12-month period ending on June 30 exceeds the CPI for the 12-month period ending June 30, 2008. The Act also states that any increase shall be rounded to the nearest dollar and that there shall be no increase in the dollar amounts if the change in the CPI since the last fee increase is less than one percent. For fiscal year 2009, the Act specified that the original annual fee for access to the Registry for each area code of data was $54 per area code, or $27 per area code of data during the second six months of an entity's annual subscription period, and that the maximum amount that would be charged to any single entity for accessing area codes of data would be $14,850.

The determination of whether a fee change is required and the amount of the fee changes involves a two-step process. First, to determine whether a fee change is required, we measure the change in the CPI from the time of the previous increase in fees. There was an increase in the fees for fiscal year 2024. Accordingly, we calculated the change in the CPI since last year, and the increase was 3.0 percent. Because this change is over the one percent threshold, the fees will change for fiscal year 2025.

Second, to determine how much the fees should increase this fiscal year, we use the calculation specified by the Act set forth above: the percentage change in the baseline CPI applied to the original fees for fiscal year 2009. The average value of the CPI for July 1, 2007, to June 30, 2008, was 211.702; the average value for July 1, 2023, to June 30, 2024, was 314.145, an increase of 48.40 percent. Applying the 48.40 percent increase to the base amount from fiscal year 2009, leads to a $80 fee for access to a single area code of data for a full year for fiscal year 2025, an increase of $2 from last year. The actual amount is $80.14 but when rounded, pursuant to the Act, $80 is the appropriate fee. The fee for accessing an additional area code for a half year increases by one dollar to $40 (rounded from $40.07. The maximum amount charged increases to $22,038 (rounded from $22,038.05).

Administrative Procedure Act; Regulatory Flexibility Act; Paperwork Reduction Act

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The fee adjustments set forth in this final rule are mandated by the Do-Not-Call Registry Fee Extension Act of 2007. Accordingly, the amendments to the TSR are merely technical in nature, making notice and comment unnecessary and contrary to the public interest. *See* 5 U.S.C. 553(b). For this reason, the requirements of the Regulatory Flexibility Act also do not apply. *See* 5 U.S.C. 603, 604.

Pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501–3521, the Office of Management and Budget (''OMB'') approved the information collection requirements in the TSR and assigned the following existing OMB Control Number: 3084–0169. The amendments outlined in this final rule pertain only to the fee provision (§ 310.8) of the TSR and will not establish or alter any record keeping, reporting, or third-party disclosure requirements elsewhere in the TSR.

List of Subjects in 16 CFR Part 310

Advertising, Consumer protection, Reporting and recordkeeping requirements, Telephone, Trade practices.

Accordingly, the Federal Trade Commission amends part 310 of title 16 of the Code of Federal Regulations as follows:

PART 310—TELEMARKETING SALES RULE

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 15 U.S.C. 6101–6108.

§ 310.8 [Amended]

■ 2. In § 310.8:
■ a. Revise paragraph (c) by:
■ i. Removing ''$78'' and adding ''$80'' in its place; and
■ ii. Removing ''$21,402'' and adding ''$22,038'' in its place;
■ b. Revise paragraph (d) by:

■ i. Removing ''$78'' and adding ''$80'' in its place; and
■ ii. Removing ''$39'' and adding ''$40'' in its place.

By direction of the Commission.

April J. Tabor,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA–2017–N–6730]

Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting for Manufacturers

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

ACTION: Notification; order granting modification to alternative.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing a minor, technical modification to an alternative that permits manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form on a quarterly basis. We refer to this alternative as the ''Voluntary Malfunction Summary Reporting Program.''

DATES: This modification applies to voluntary summary reports for reportable malfunction events that manufacturers become aware of on or after August 29, 2024.

FOR FURTHER INFORMATION CONTACT: Michelle Rios, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1116, Silver Spring, MD 20993–0002, 301–796–6107; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Every year, FDA receives over two million MDRs of suspected device-associated deaths, serious injuries, and malfunctions. The Agency's MDR program is one of the postmarket surveillance tools FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Malfunction reports represent most of the MDRs FDA receives on an annual basis.

Medical device reporting requirements for manufacturers are set forth in section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) and the regulations contained in part 803 (21 CFR part 803). Among other things, part 803 requires the submission of an individual MDR when a manufacturer becomes aware of information, from any source, that reasonably suggests that one of its marketed devices malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§§ 803.10(c)(1) and 803.50(a)(2)). Throughout this document, we refer to such malfunctions as ''reportable malfunctions'' or ''reportable malfunction events.''

Under § 803.19, FDA may grant exemptions or variances from, or alternatives to, any or all of the reporting requirements in part 803, and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. FDA may grant such modifications upon request or at its discretion, and when granting such modifications, FDA may impose other reporting requirements to ensure the protection of the public health (see § 803.19(c)).

In accordance with section 519(a)(1)(B)(i) of the FD&C Act and § 803.19, FDA granted to manufacturers of devices in eligible product codes, as identified in the FDA Product Classification Database (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*) on August 17, 2018, an alternative that permits submission of malfunction summary reports on a quarterly basis for certain device malfunctions. The Agency published a document of the alternative in the **Federal Register** (83 FR 40973, August 17, 2018). Consistent with that document, FDA subsequently determined that additional product codes are eligible for the Voluntary Malfunction Summary Reporting Program (the program) and granted the same alternative to manufacturers of devices in those product codes.

FDA believes that for the devices in eligible product codes, quarterly, summary reporting in accordance with the conditions of the alternative is as effective as the current MDR regulatory requirements for purposes of identifying and monitoring potential device safety concerns and device malfunctions. The program allows manufacturers to submit summary reports with event narratives that help FDA more efficiently process malfunction reports and identify malfunction trends. In addition, FDA's determination of product code eligibility and the conditions of participation in the program serve to require submission of individual 30-day or 5-day malfunction reports in circumstances where such reports are necessary to protect public health.

II. Modification to Malfunction Summary Reporting Format for the Voluntary Malfunction Summary Reporting Program

Under § 803.19(d), FDA ''may revoke or modify in writing an exemption, variance, or alternative reporting requirement if we determine that revocation or modification is necessary to protect the public health.''

To meet the conditions of the Voluntary Malfunction Summary Reporting Program (VMSR), manufacturers of devices in eligible product codes who elect to participate in the program must submit summary malfunction reports electronically using Form FDA 3500A (Ref. 1) pursuant to the malfunction reporting summary format described in the document published in 2018 (83 FR 40973, August 17, 2018). However, since the program began in 2018, FDA has revised Form FDA 3500A. For example, FDA has added a ''check box'' and field in which the manufacturer may specifically indicate that a report is a ''summary report'' and enter the number of events being summarized. Additionally, FDA has added a field that facilitates clearer identification of a report as a VMSR summary reports. Use of these features of the revised Form 3500A allows FDA to more efficiently identify VMSR summary reports and the number of events summarized, enabling more effective review of these reports. Certain fields in the Form FDA 3500A have also changed so that they no longer align exactly with the instructions describing the required malfunction reporting summary format for the program. In addition, FDA's MDR references for adverse event codes have been updated.

Revising the required format for summary malfunction reports submitted under the VMSR Program to align with the most current Form FDA 3500A and adverse event codes will avoid confusion and help ensure the accuracy and consistency of information in summary malfunction reports. Consistent, accurate summary reports are necessary to ensure that both FDA