TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section or other citation; activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
680.1(b)(3)(iv); Requirement to notify FDA when certain diseases are detected in source materials.	NA	1	1	1	2	2
601.12; Amendments/Resubmissions	356h	170	27.888	4741	20	94,820
Section 402(j)(5)(B) of the PHS Act; Certification to accompany biological product applications.	3674	1,291	1	1,291	0.28 (17 minutes)	358
Total						907,806

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The numbers in this column have been rounded to the nearest whole number.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosures	Total hours [2]
601.6(a); Requirement to notify selling agents and distributors upon suspension of license.	1	20	20	0.33 (20 minutes)	7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The number in this column has been rounded to the nearest whole number.

Our estimated burden for the information collection reflects an overall increase of 467,907 hours and a corresponding increase in responses. Most of our adjustment reflects an increase in the number of annual submissions that we have received under §§ 601.12(b)(1) and (3), (e), and (f)(4), and 601.45 over the last few years. We attribute the remaining increase (358 hours) to submissions of Form FDA 3674.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03508 Filed 2–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0957]

Compliance Policy Guide Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the compliance policy guide (CPG) Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power. The Agency is taking this action because the CPG identified in this notice contains policies that have been superseded by a subsequent FDA action.

DATES: The withdrawal is effective February 21, 2023.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION: We are announcing the withdrawal of the CPG entitled ''Compliance Policy Guide Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power, 21 CFR 1050.10(c)(1)(ii).'' On January 20, 2023, FDA issued a final rule entitled ''Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products'' (88 FR 3638). The final rule repealed 21 CFR 1050.10, which includes performance standards for ultrasonic therapy products. Therefore, the policies in CPG Sec. 397.100 are no longer applicable, and this CPG is being withdrawn.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03509 Filed 2–17–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–1939]

Determination That TOPAMAX (Topiramate) Sprinkle Capsules, 50 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that TOPAMAX (topiramate) sprinkle capsules, 50 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for topiramate, sprinkle capsules, 50 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222,