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 The Agency is taking this action because the CPG identified in this notice contains policies that have been superseded by a subsequent FDA action.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]

BILLING CODE 4164–01–P

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,

Silver Spring, MD 20993–0002, 240–402–4078, *Alexandria.Fujisaki@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TOPAMAX (topiramate) sprinkle capsules, 50 mg, is the subject of NDA 020844, held by Janssen Pharmaceuticals, Inc., and initially approved on October 26, 1998. TOPAMAX is indicated for epilepsy (initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older) and preventive treatment of migraine in patients 12 years of age and older.

Janssen Pharmaceuticals, Inc., has never marketed TOPAMAX (topiramate) sprinkle capsules, 50 mg. In previous instances (see, *e.g.,* 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated August 17, 2022 (Docket No. FDA–2022–P–1939), under 21 CFR 10.30, requesting that the Agency determine whether TOPAMAX (topiramate) sprinkle capsules, 50 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TOPAMAX (topiramate) sprinkle capsules, 50 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TOPAMAX (topiramate) sprinkle capsules, 50 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TOPAMAX (topiramate) sprinkle capsules, 50 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TOPAMAX (topiramate) sprinkle capsules, 50 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to TOPAMAX (topiramate) sprinkle capsules, 50 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03516 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–2023–D–0044]

Product-Specific Guidance Meetings Between the Food and Drug Administration and Abbreviated New Drug Applicants Under the Generic Drug User Fee Act; 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 entitled ''Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA.'' This draft guidance provides recommendations to industry on product-specific guidance (PSG) meetings between FDA and a prospective applicant preparing to submit to FDA or an applicant that has submitted to FDA an abbreviated new drug application (ANDA) under the Federal Food, Drug and Cosmetic Act (FD&C Act). Specifically, this draft guidance provides information on requesting and conducting PSG meetings with FDA (PSG teleconferences, pre-submission PSG meetings, and post-submission PSG meetings), as contemplated in the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III commitment letter). This draft guidance is intended to provide procedures that will promote well-managed PSG meetings and help ensure that such meetings are scheduled and conducted in accordance with the time frames set forth in the GDUFA III commitment letter.

DATES: Submit either electronic or written comments on the draft guidance by April 24, 2023 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:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://*