

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
ECE Director or Administrator .....	Recruitment Letter .....	1,140	1	5/60	95
ECE Director or Administrator .....	Web/Mail Survey .....	627	1	30/60	314
Total .....	.....	.....	.....	.....	409

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-0803]

**Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee; Renewal**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Technical Electronic Product Radiation Safety Standards Committee (Committee) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until December 24, 2020.

**DATES:** Authority for the Technical Electronic Product Radiation Safety Standards Committee would have expired on December 24, 2018, unless the Commissioner formally determined that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993-0002, 301-796-6875, [Patricio.Garcia@fda.hhs.gov](mailto:Patricio.Garcia@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Committee. The Committee is a non-discretionary Federal advisory

committee established to provide advice and consultation to the Commissioner. The Commissioner of Food and Drugs is charged with the administration of the Radiation Control for Health and Safety Act of 1968. This act creates the Committee and requires the Commissioner to consult with the Committee before prescribing standards for radiation emissions from electronic products. This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products and may recommend electronic product radiation safety standards to the Commissioner for consideration.

The Committee shall consist of a core of 15 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the Committee by appropriate action prior to its expiration. The core of voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/default.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light

of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Commissioner of Food and Drugs.*

[FR Doc. 2019-06360 Filed 4-1-19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-P-2754]

**Determination That ONFI (Clobazam) Tablets, 5 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 or Agency) has determined that ONFI (clobazam) tablets, 5 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) that refer to the drug product, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6206, Silver Spring, MD 20993-0002, 240-402-0978.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate