FERC Form No. 3–Q, Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies

OMB Control No.: 1902–0205.

Abstract: The FERC Form No. 3–Q is a quarterly financial and operating report for rate regulation, market oversight analysis, and financial audits which supplements the (a) FERC Form Nos. 1 and 1–F, for the electric industry, or the (b) FERC Form No. 2 (Annual Report for Major Natural Gas Companies; OMB Control No. 1902–0028) and FERC Form No. 2–A (Annual Report for Nonmajor Natural Gas Companies; OMB Control No. 1902–0030), for the natural gas industry. The FERC Form No. 3–Q is submitted for all Major and Nonmajor electric utilities, licensees, and natural gas companies.[6]

FERC Form No. 3–Q includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Income and Statement of Retained Earnings,
- Statement of Cash Flows,
- Statement of Comprehensive Income and Hedging Activities, and
- Supporting schedules containing supplementary information.

Electric respondents report:

- Revenues and the related quantities of electric sales and electricity transmitted,
- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data; and
- Other statistical information.

Natural gas respondents include:

- Monthly and quarterly quantities of gas transported and associated revenues,
- Storage, terminaling and processing services,
- Natural gas customer accounts and details of service, and
- Operational expenses, depreciation, depletion and amortization of gas plant.

Type of Respondent: Major and nonmajor electric utilities, licensees, and natural gas companies.

Estimate of Annual Burden: The estimated annual burden and cost (as rounded) follow. (The estimated hourly cost used for the FERC Form No. 3–Q is $79 (for wages plus benefits) and is described above, under the FERC Form No. 1.):

FERC Form No. 3–Q

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours and cost per response (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Annual cost per respondent ($) (5) ÷ (1)
FERC 3–Q (electric)	212	3	636	168 hrs.; $13,272	106,848 hrs.; $8,440,992	$39,816
FERC 3–Q (natural gas)	165	3	495	167 hrs.; $13,193	82,665 hrs.; $6,530,535	$39,579
Total for FERC 3–Q			1,131		189,513 hrs.; $14,971,527.	

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: April 30, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–09297 Filed 5–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1774]

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' This guidance document provides an overview of the mechanisms available to applicants through which they can request feedback from or a meeting with FDA regarding potential or planned medical device investigational device exemption (IDE) applications, premarket approval applications (PMAs), humanitarian device exemption (HDE) applications, evaluation of automatic class III designations (De Novo requests), premarket notification (510(k)) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications, Dual 510(k) and CLIA Waiver by Application Submissions, Accessory Classification Requests, and certain investigational new drug (IND) applications and biologics license applications (BLAs).

DATES: The announcement of the guidance is published in the **Federal Register** on May 7, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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://www.regulations.gov* will be posted to the docket unchanged. Because your

[6] 18 CFR 260.1(b) states that for natural gas companies as defined by the Natural Gas Act, Major pertains to a company whose combined gas transported or stored for a fee exceed 50 million Dth in each of the three previous calendar years. 18 CFR 260.2(b) states that for natural gas companies as defined by the Natural Gas Act, Non-Major pertains to a company not meeting the filing threshold for FERC Form No. 2, but having total gas sales or volume transactions exceeding 200,000 Dth in each of the three previous calendar years.

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1774 for ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6524; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The pre-IDE program was established in 1995 to provide applicants a mechanism to obtain FDA feedback on future IDE applications prior to their submission. Over time, the pre-IDE program evolved to include feedback on PMA applications, HDE applications, De Novo requests, and 510(k) submissions, as well as to address whether a clinical study requires submission of an IDE.

To capture this evolution, the Secretary of Health and Human Services' 2012 Commitment Letter to Congress regarding the Medical Device User Fee Amendments of 2012 (MDUFA III) included FDA's commitment to institute a structured process for managing these interactions, referring to them as ''Pre-Submissions.'' The Pre-Submission Guidance, published February 18, 2014, implemented the broader Q-Submission (Q-Sub) Program, which includes Pre-Submissions (Pre-Subs), as well as additional opportunities to engage with FDA.

As part of the Medical Device User Fee Amendments of 2017 (MDUFA IV), industry and the Agency agreed to refine the Q-Sub Program with changes related to the scheduling of Pre-Sub meetings and a new performance goal on the timing of FDA feedback on Pre-Subs. This guidance reflects those changes and clarifies other elements of the Q-Sub program.

This guidance document provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with FDA regarding potential or planned medical device IDE applications, PMAs, HDE applications, De Novo requests, 510(k) Submissions, CLIA Waiver by Application, Dual 510(k) and CLIA Waiver by Application Submissions, Accessory Classification Requests, and certain INDs and BLAs submitted to the Center for Biologics Evaluation and Research. FDA considered comments received on the draft guidance, which was announced in the **Federal Register** of June 7, 2018 (83 FR 26482). FDA revised the guidance as appropriate in response to the comments. This guidance supersedes the document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff,'' issued on September 29, 2017.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1677 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part or guidance	Topic	OMB control No.
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Requests	0910–0844
''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Waivers	0910–0598
''Medical Device Accessories—Describing Accessories and Classification Pathways''.	Accessories	0910–0823
312	Investigational New Drug Application	0910–0014
601	Biologics License Application	0910–0338
807, subpart E	Premarket Notification	0910–0120
812	Investigational Device Exemption	0910–0078
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Use Device; Humanitarian Device Exemption.	0910–0332

Dated: May 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09338 Filed 5–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: June 3, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, Rockville, MD 20852.

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7770, Bethesda, MD 20892, (301) 455–1761, *kellya2@csr.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.

Date: June 3–4, 2019.

Time: 8:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 500–5829, *sechu@csr.nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Bacterial Pathogenesis Study Section.

Date: June 3–4, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–435–1149, *marci.scidmore@nih.gov*.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section.

Date: June 4–5, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Warwick Denver, 1776 Grant Street, Denver, CO 80203.

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451–6319, *rojasr@mail.nih.gov*.