Based on data shared by another Federal Agency, FDA estimates that 135 establishments will initially submit one report, and then will submit confirmation or update reports on a semiannual basis.

FDA estimates that the confirmation or updating of registration information as required by section 905 will take 12 minutes annually per confirmation or update per establishment.

FDA estimates that the submission of product listings required by section 905 for each establishment will take 2 hours initially. FDA also estimates that the confirmation or updating of product listing information required by section 905 will take 48 minutes annually for two confirmations or updates per establishment.

FDA estimates that obtaining an optional Dun and Bradstreet D–U–N–S number will take 0.5 hours, and that 8 respondents (1 percent × 135 = 1.35 of establishments required to register under section 905, and 5 percent × 135 = 6.75 of submitters required to list ingredients under section 904) will not already have a Dun and Bradstreet D–U–N–S number.

FDA estimates that the submission of ingredient listing information as required by section 904 of the act will take 3 hours per tobacco product.

Dated: July 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18410 Filed 7–27–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2537]

Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; notice of draft guidance availability, request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), is announcing the availability of a draft guidance for industry entitled ''Request for Quality Metrics'' and a public meeting regarding the Agency's plans associated with a quality metrics reporting program. The draft guidance and public meeting are intended to gain stakeholders' perspectives on various aspects of the development and planned implementation of a quality metrics program launched under the authority of the Food, Drug, and Cosmetic Act (the FD&C Act). The guidance includes an explanation of how FDA intends to use quality metrics data to further develop the FDA's risk-based inspection scheduling, to identify situations in which there may be a risk for drug supply disruption, to improve the efficiency and effectiveness of establishment inspections, and to improve FDA's evaluation of drug manufacturing and control operations. FDA expects that the initial use of the metrics will be to consider a decreased surveillance inspection frequency for certain establishments. For example, establishments that have highly controlled manufacturing processes have the potential to be inspected less often (as a lower priority for inspection) than similar establishments that demonstrate uncontrolled processes (as a higher priority for inspection). In addition, FDA intends to consider whether these metrics may provide a basis for FDA to use improved risk-based principles to determine the appropriate reporting category for postapproval manufacturing changes. FDA intends to consider the input from this public meeting as we finalize this guidance and the planned implementation of this program, including FDA's initial set of requests for quality metrics data.

DATES: The meeting will be held on August 24, 2015, from 8:30 a.m. to 5 p.m. The meeting may be extended or end early depending on the level of public participation. Register to attend or present at the meeting by August 7, 2015, (see section V.C. for information on how to register or make a presentation at the meeting). If you cannot attend in person, information about how you can access a live Web cast will be located at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm.*

Submit either electronic or written comments concerning the draft guidance and collection of information proposed in the draft guidance by September 28, 2015.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 Section B/C), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, email: *Althea.Cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

More than a decade ago, FDA launched an initiative to encourage the implementation of a modern, risk-based pharmaceutical quality assessment system. As part of this initiative, and in recognition of the increasing complexity of pharmaceutical manufacturing, FDA developed a 21st century vision for manufacturing and quality with input from academia and industry. The desired state was described as follows: ''A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.'' [1]

There has been significant progress toward this vision in the intervening

[1] See ''FDA Pharmaceutical Quality Oversight: One Quality Voice'' at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM442666.pdf.*

years, as evidenced by programs and guidance from FDA around major initiatives such as pharmaceutical development and quality by design (QbD), quality risk management and pharmaceutical quality systems, process validation, and process analytical technology (PAT), among others. These programs and guidances are intended to promote effective use of the most current pharmaceutical science and engineering principles and knowledge throughout the lifecycle of a product.

Despite these achievements, however, we have not fully realized our 21st century vision for manufacturing and quality—there continue to be indicators of serious product quality defects. The Agency has found that the majority of drug shortages stem from quality concerns—substandard manufacturing facilities or processes are discovered, or significant quality defects are identified in finished product, necessitating remediation efforts to fix the issue, which in turn, may interrupt production, and cause a shortage of drugs.[2] Taking action to reduce drug shortages remains a top priority for FDA.

The continued existence of product quality issues may point to increased complexities in the supply chain, a lack of innovation in manufacturing, a failure to adopt modern manufacturing technologies and robust quality management systems, or other factors. Title VII of the Food and Drug Administration Safety and Innovation Act (FDASIA) amended the FD&C Act to provide FDA with a number of new authorities to drive safety and quality throughout the drug supply chain. Section 706 of FDASIA amended section 704(a) of the FD&C Act (21 U.S.C. 374(a)) by adding section 704(a)(4), under which FDA may require the submission of any records or other information that FDA may inspect under section 704 of the FD&C Act, in advance or in lieu of an inspection, by requesting the records or information from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug. As described in the draft guidance, under this authority, FDA intends to make an initial set of requests for quality metrics data to owners and operators of certain human drug establishments. FDA intends to make its requests at the time the guidance is finalized and to provide notice of its requests in the **Federal Register**. FDA would use the data it receives to calculate quality metrics and to inform decisions about how to develop its program. FDA may add to, revise, or remove quality metrics data and establishments in such future requests to reflect the Agency's understanding of current manufacturing and establishment considerations and the utility of the data received to date.

FDA used the following criteria for the selection of the quality metrics described in the guidance: Objective, subject to inspection under section 704 of the FD&C Act, and valuable in assessing the overall state of quality of the product and process, commitment to quality by the manufacturer, and the health (*i.e.,* effective functioning) of the associated Pharmaceutical Quality System(s), while avoiding any undue reporting burden.

CGMP regulations for human drugs expect an ongoing program to maintain and evaluate product and process data that relate to product quality (21 CFR 211.180(e)). Manufacturers are expected to use a quality program in order to support process validation, and the metrics described in this guidance could be a part of such a program. As discussed in the guidance, FDA encourages manufacturers to routinely use additional quality metrics beyond the metrics described in this guidance in performing these evaluations.

FDA intends to use quality metrics data to further develop the FDA's risk-based inspection scheduling, to identify situations in which there may be a risk for drug supply disruption, to improve the efficiency and effectiveness of establishment inspections, and to improve FDA's evaluation of drug manufacturing and control operations. FDA expects that the initial use of the metrics will be to consider a decreased surveillance inspection frequency for certain establishments. For example, establishments that have highly controlled manufacturing processes have the potential to be inspected less often (as a lower priority for inspection) than similar establishments that demonstrate uncontrolled processes (as a higher priority for inspection). In addition, FDA intends to consider whether these metrics may provide a basis for FDA to use improved risk-based principles to determine the appropriate reporting category for postapproval manufacturing changes.

In the context of developing this program, to identify some types of mutually useful and objective quality metrics, FDA has consulted with stakeholders through various trade and professional association meetings, and a **Federal Register** document we published on February 12, 2013 (78 FR 9928) soliciting initial input on the use of manufacturing quality metrics as it relates to drug shortages. These efforts have generated several categories of quality-related information that CDER and CBER have considered in developing the quality metrics discussed in the guidance.

As described in the guidance, FDA intends to collect and use quantitative quality metrics data to calculate four quality metrics. Notably, FDA has considered requesting data on the ''Right First Time'' metric, which is a measure of the rework/reprocessing rate or the number of lots released without any processing deviations. We believe that a Right First Time metric can be a useful metric for establishments to measure as part of their own quality metrics program and a leading indicator for product quality. However, as part of our stakeholder consultation, we have also received mixed industry feedback on how to define this metric, whether this metric may be less relevant for finished dosage forms than for active pharmaceutical ingredient (API) manufacturing (where rework is more common), and whether this metric is suitably robust for use in our program. We are requesting further input on this topic (see section V.B.).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on request for quality metrics. 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.

II. Specific Request for Comments and Information

In addition to comments on the guidance generally, FDA is requesting comments and related supporting information on the following topics, as described in the draft guidance: (1) Optional metrics related to quality culture and process capability/performance, (2) frequency of quality metrics data reporting, (3) an alternative approach to reduce the reporting burden based on the data collection timeframe, and (4) an alternative approach that would allow inclusion of a limited text field for data points or metrics. FDA has described these potential alternative approaches in the draft guidance and is

[2] In 2012, for example, based on information collected from manufacturers, FDA determined that 66 percent of disruptions in drug manufacturing were the result of either (1) efforts to address product-specific quality failures or (2) broader efforts to remediate or improve an unsafe manufacturing facility. ''FDA's Strategic Plan for Preventing and Mitigating Drug Shortages'', see figure 2, at *http://www.fda.gov/downloads/drugs/drugsafety/drugshortages/ucm372566.pdf.*

seeking public comment on these and any other alternative approaches.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

The draft guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Request for Quality Metrics; Guidance for Industry.

Description: FDA intends to use quality metrics data to further develop the FDA's risk-based inspection scheduling, to identify situations in which there may be a risk for drug supply disruption, to improve the efficiency and effectiveness of establishment inspections, and to improve FDA's evaluation of drug manufacturing and control operations. FDA expects that the initial use of the metrics will be to consider a decreased surveillance inspection frequency for certain establishments. For example, establishments that have highly controlled manufacturing processes have the potential to be inspected less often (as a lower priority for inspection) than similar establishments that demonstrate uncontrolled processes (as a higher priority for inspection). In addition, FDA intends to consider whether these metrics may provide a basis for FDA to use improved risk-based principles to determine the appropriate reporting category for postapproval manufacturing changes.

Section 704(a)(4)(A) of the FD&C Act, added by section 706 of FDASIA, authorizes FDA to request from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug in advance or in lieu of an inspection any records or other information that we may inspect under section 704 of the FD&C Act, provided that we request submission of the information within a reasonable time frame, within reasonable limits, and in a reasonable manner. The draft guidance is intended to describe a set of requests for data under section 704(a)(4) of the FD&C Act that FDA intends to give notice of in the **Federal Register** at the time the guidance is finalized. In general, the information needed to respond to FDA's proposed requests is developed and maintained in the course of manufacturing drugs under existing current good manufacturing practice (CGMP) for finished pharmaceuticals in part 211 (21 CFR part 211), and for APIs under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), and could be reviewed during an FDA inspection of a drug establishment. FDA has OMB approval for the information collection currently required under part 211 (OMB control number 0910–0139) and, in table 2, we have calculated the burden for preparing and maintaining the information collection for APIs as currently required under section 501(a)(2)(B) of the FD&C Act but not currently included under OMB control number 0910–0139.

FDA intends to request quality metrics data from owners and operators of certain establishments registered under section 510 of the FD&C Act (21 U.S.C. 360), as described in the draft guidance. FDA intends to request that such establishments compile reports containing the following quality metrics data, segregated by quarter, by product, and establishment:

- The number of lots attempted of the product.
- The number of specification-related rejected lots of the product, rejected during or after manufacturing.
- The number of attempted lots pending disposition for more than 30 days.
- The number of out-of-specification (OOS) results for the product, including stability testing.
- The number of lot release and stability tests conducted for the product.
- The number of OOS results for lot release and stability tests for the product which are invalidated due to lab error.
- The number of product quality complaints received for the product.
- The number of lots attempted which are released for distribution or for the next stage of manufacturing the product.
- If the associated annual product reviews (APRs) or product quality reviews (PQRs) were completed within 30 days of annual due date for the product.
- The number of APRs or PQRs required for the product.

In addition to the baseline metrics described previously, FDA is requesting public comment on whether to include the option of submitting additional, optional metrics as evidence of manufacturing robustness and a commitment to quality:

- Senior Management Engagement—Was each APR or PQR reviewed and approved by the following: (1) The head of the quality unit, (2) the head of the operations unit, (3) both, or (4) neither?
- Corrective Action and Preventive Action (CAPA) Effectiveness—What percentage of your corrective actions involved re-training of personnel (*i.e.,* a root cause of the deviation is lack of adequate training)?
- Process Capability/Performance—A ''yes'' or ''no'' value of whether the establishment's management calculated a process capability or performance index for each critical quality attribute as part of that product's APR or PQR.
- Process Capability/Performance—A ''yes'' or ''no'' value of whether the establishment's management has a policy of requiring a CAPA at some lower process capability or performance index.
- Process Capability/Performance—If ''yes'' to the previous question—What is the process capability or performance index that triggers a CAPA? If ''no'' to the previous question—please do not respond.

We estimate the submission of approximately 63,000 product reports to FDA containing the 15 quality metrics data outlined in this document and described in the draft guidance (''Total Annual Reponses'' in table 1). We estimate that approximately 6,300 establishments will compile and submit these reports, including covered

establishments, reporting establishments, and unregistered foreign establishments, as described in the draft guidance (''Number of Respondents'' in table 1). We specifically request comment on our estimate of 6,300 establishments and the types of establishments that will participate in compiling and reporting quality metrics data.

Our estimate of 63,000 reports is based on the following: Approximately 25,000 reports for drugs subject to approved applications (that is, drugs subject to either approved applications under section 505 of the FD&C Act (21 U.S.C. 355) or under section 351 of the PHS Act, or covered by a submission to a drug master file that is intended to support an application, and approximately 38,000 reports for drugs not subject to approved applications (that is, drugs not subject to either approved applications under section 505 of the FD&C Act or under section 351 of the PHS Act (*e.g.,* drugs marketed pursuant to an OTC monograph and marketed unapproved drugs)).

Our estimate of 6,300 establishments is based on data from FDA's Document Archiving, Reporting & Regulatory Tracking System and the Electronic Drug Registration and Listing System. We estimate that reporting the quality metrics data described previously for each affected product will take approximately 10.6 hours (''Average Burden per Response'' in table 1). This is a weighted average of the estimate for ''drugs subject to approved applications'' (finished product and API) (15.75 hours) and ''drugs not subject to approved applications'' (finished product and API) (7 hours). The time estimate for application and non-application products differs because the groupings are different (*e.g.,* different strengths are grouped in an application and are not grouped for national drug code). These burden hour estimates are based on information provided by CGMP regulatory compliance experts at FDA and in industry. Therefore, we estimate approximately 667,800 total burden hours for compiling and reporting quality metrics data under the draft guidance (''Total Hours'' in table 1). We believe that the estimated burden for the initial set of requests represents a conservative estimate of the annual burden of responding to any future information requests under the quality metrics program.

The burden hour estimate includes the time for compiling information that we understand is currently developed and maintained in the course of manufacturing drugs in compliance with part 211 and section 501(a)(2)(B) of the FD&C Act, and the time for populating spreadsheet(s) for reporting to FDA. The estimate does not include burden hours currently approved under OMB control number 0910–0139 for information collection under part 211. In table 2, we have calculated the burden for information collection for APIs as currently required under section 501(a)(2)(B) of the FD&C Act but not currently included under OMB control number 0910–0139.

The draft guidance requests that all reports be submitted through the FDA Electronic Submission Gateway (ESG). We are not estimating any additional burden associated with accessing the ESG because reporting establishments, which are subject to FDA's establishment registration and drug listing regulations (21 CFR part 207), are required to use the ESG to submit information, and the burdens associated with these submissions are approved under OMB control number 0910–0045. To date, we have not identified any reporting establishments that are not already reporting to the ESG.

In table 1, we estimate the reporting burden for the information collection in the draft guidance.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Draft guidance for industry on request for quality metrics	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Collecting and Reporting to FDA Quality Metric Inputs	6,300	10	63,000	10.6 hours	667,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In table 2, we estimate the recordkeeping burden for preparing and maintaining CGMP records for APIs that are not currently included under OMB control number 0910–0139.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Section 501(a)(2)(B) of the FD&C Act	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Preparing and Maintaining CGMP Records for APIs (not currently included under OMB control number 0910–0139)	1,260	256	322,560	.82 hours	264,499

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Title: Request for Quality Metrics; Public Meeting.

The information collection associated with the public meeting is exempt from OMB regulations on the PRA as follows: 5 CFR 1320.3(h)(8) (exemption from the definition of ''information''): Facts or opinions obtained or solicited at or in connection with public hearings or meetings. 5 CFR 1320.3(h)(4) (exemption from the definition of ''information''): Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment.

V. Attendance and/or Participation at the Public Meeting

A. Purpose and Scope of the Meeting

The purpose of this meeting and public docket is for CDER and CBER to hear from stakeholders any questions, concerns, and suggestions regarding the proposed plans for the scope and implementation of the quality metrics reporting program proposed in this guidance.

B. Questions to Stakeholders

FDA seeks input from stakeholders and other members of the public on the following meeting questions:

1. Are there other objective metrics that FDA should request in advance of or in lieu of an inspection that FDA should collect to improve our understanding of products and establishments for purposes of more informed, risk-based inspection scheduling and identification of potential product shortages?
2. Are the definitions of the metrics and associated data requests selected adequate and clear?
3. Are the metrics requested from each business segment/type clear and appropriate?
4. Should the Agency explore collecting metrics from high-risk excipient producers, and if so, which excipients should be considered high-risk and what metrics should apply?
5. Should the Agency explore collecting metrics from the medical gas manufacturing industry?
6. Should the Agency add the ''Right First Time'' metric (see section I.), and if so, should the definition be a rework/reprocessing rate or a measure of lots manufactured without processing deviations?
7. What data standards/mechanisms would be useful to aid reporting and how should the submissions be structured?
8. Are there reporting hurdles to collecting metrics by reporting establishment/product (segmented by site) versus by site (segmented by product), and how can they be overcome?
9. FDA may consider whether to require the submission of quality metrics on a recurring basis. How frequently should metrics be reported and/or segmented within the reporting period (*e.g.,* annually, semiannually, or quarterly)?

C. Meeting Participation and Request To Present

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Web cast (see *Streaming Web Cast of the Public Meeting*)) and/or present at the meeting, please register for the meeting and/or make a request for oral presentations or comments by visiting *https://qualitymetrics-public-meeting.eventbrite.com* on or before August 7, 2015. The registration request should contain complete contact information for each attendee (*i.e.,* name, title, affiliation, address, email address, telephone number, and priority number(s)). Those without email access can register by contacting Althea Cuff by August 7, 2015 (see **FOR FURTHER INFORMATION CONTACT**).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address (see section V.B.). This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to Althea Cuff at *Althea.Cuff@fda.hhs.gov* on or before August 7, 2015. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make a presentation.

Persons registered to make an oral presentation are encouraged to arrive at the meeting room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the meeting and other background materials will be made available 3 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm*. If you need special accommodations because of a disability, please contact Althea Cuff (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Meeting Registration and Request to Present: The meeting is free and seating will be on a first-come, first-served basis. If you wish to attend or make an oral presentation, see section V.C. for information on how to register and the deadline for registration. If you cannot attend in person, information about how you can access a live Web cast will be located at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm*.

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may also be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Streaming Web Cast of the Public Meeting: For those unable to attend in person, FDA will provide a live Web cast of the meeting. To join the meeting via the Web cast, please go to *https://collaboration.fda.gov/qmpm2015/*. An agenda will be posted on the FDA Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm* prior to the meeting.

Docket Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document to the public docket (see **ADDRESSES**) by (see **DATES**). Given that time will be limited at the public meeting, FDA encourages all interested persons to comment in writing to ensure that their comments are considered.

VI. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

Dated: July 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18448 Filed 7–27–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will hold a meeting. The meeting will be open to the public.